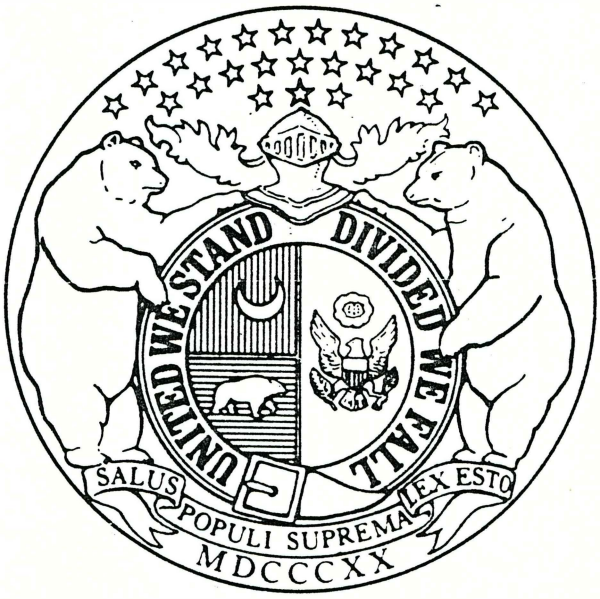
MISSOURI

STATE GUIDELINES



ACQUIRED IMMUNE DEFICIENCY SYNDROME

State Agency AIDS Task Force
John R. Bagby, Jr., Ph.D., Chairman

Missouri Commission on Human Rights
Office of Administration
University of Missouri
Department of Health
Department of Public Safety
Department of Social Services
Department of Corrections and Human Resources
Department of Elementary and Secondary Education

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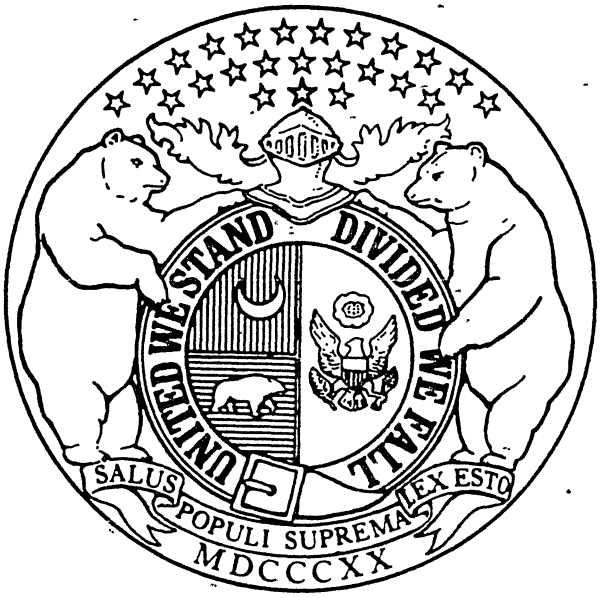

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M I S S O U R I
S T A T E G U I D E L I N E S

A C Q U I R E D I M M U N E
D E F I C I E N C Y S Y N D R O M E (A I D S)

May 1986

State Agency AIDS Task Force
John R. Bagby, Jr., Ph.D., Chairman

Missouri Commission on Human Rights
Office of Administration
University of Missouri
Department of Health
Department of Mental Health
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Department of Social Services
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MISSOURI STATE GUIDELINES/

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)
May 1986

PURPOSE: These guidelines establish a common basis for all state agency actions regarding AIDS and HTLV-III infection. This will assure the appropriate management of infection or disease in patients, clients, or agency personnel. An appendix may be added by any agency to address problems or conditions unique to that agency. Each appendix must be submitted to the Task Force for review and approval prior to addition to this document.

BACKGROUND: Since the first diagnosis of the Acquired Immune Deficiency Syndrome in the United States (1981), thousands of Americans have been physically and emotionally affected by this disease that results from a viral infection, leaving the body immunologically deficient. The fatality rate is very high and over 50 percent of the individuals diagnosed with AIDS since 1981 have died.

AIDS is caused by a retrovirus known as Human T-Lymphotropic Virus (HTLV-III), also known as the Lymphadenopathy Associated Virus (LAV). An Enzyme Linked Immunosorbent Assay (ELISA) is used to detect infection by the virus by recognizing the presence of antibody. A confirmed positive test result indicates an infection by HTLV-III but <u>does not</u> indicate whether an individual will develop AIDS.

Infections which result from the lack of an adequate immune response are termed "opportunistic" and those which are most common in AIDS patients are <u>Pneumocystis carinii</u> pneumonia (PCP), and Kaposi's sarcoma (KS), a rare type of cancer.

Infection with HTLV-III may result in a spectrum of conditions ranging from minor to extreme in severity: 1) asymptomatic - having positive HTLV-III antibody test, yet no symptoms suggestive of AIDS or AIDS Related Complex (ARC); 2) presence of other laboratory abnormalities with or without related symptoms; 3) neurologic manifestations; 4) Oral Viral Hairy Leukoplakia; 5) ARC - AIDS Related Complex - involving fever, weight loss, enlarged lymph nodes, persistent diarrhea, night sweats or fatigue, etc., which may or may not be precursors of AIDS; 6) AIDS - involving opportunistic infections which have taken advantage of the seriously damaged immune system.

Acquisition of the HTLV-III virus is through the transfer of blood or semen. Five groups are considered to be at high risk of acquiring the virus: homosexual or bisexual males (75 percent); intravenous drug abusers (15 percent); persons who have had blood transfusions (two percent); hemophiliacs (one percent); heterosexual contact to an infected individual (one percent).

The HTLV-III virus has been isolated from blood, semen, saliva, tears and urine, yet the transfer of the virus does not appear to occur through means other than direct exposure to semen, blood or blood products.

GUIDELINES: The State of Missouri will utilize the following guidelines, appendices and departmental policy supplements in all state agencies for the prevention and risk reduction of AIDS and testing for infection with the virus:

A. RECOMMENDATIONS FOR PREVENTING TRANSMISSION OF INFECTION WITH HUMAN T-LYMPHOTROPIC VIRUS TYPE III/LYMPHADENOPATHY-ASSOCIATED VIRUS IN THE WORKPLACE, published in MMWR, November 15, 1985, pertains to preventing transmission of infections in the workplace. (MMWR, November 15, 1985; Appendix I.)

B. RECOMMENDATIONS FOR ASSISTING IN THE PREVENTION OF PERINATAL TRANSMISSION OF HUMAN T-LYMPHOTROPIC VIRUS TYPE III/LYMPHADENOPATHY-ASSOCIATED VIRUS AND ACQUIRED IMMUNODEFICIENCY SYNDROME appeared in MMWR, December 6, 1985. (Appendix II.)

C. EDUCATION AND FOSTER CARE OF CHILDREN INFECTED WITH HUMAN T-LYMPHOTROPIC VIRUS TYPE III/LYMPHADENOPATHY-ASSOCIATED VIRUS published in MMWR, August 30, 1985, pertains to placement of children infected with the HTLV-III virus in educational and foster care facilities. (MMWR, August 30, 1985; Appendix III.)

D. TESTING DONORS OF ORGANS, TISSUES, AND SEMEN FOR ANTIBODY TO HUMAN T-LYMPHOTROPHIC VIRUS TYPE III/LYMPHADENOPATHY-ASSOCIATED VIRUS published in MMWR, May 24, 1985, pertains to the prevention of contamination of the blood supply and recognition of HTLV-III infection in body fluids and organs. (MMWR, May 24, 1985; Appendix IV.)

E. REVISED PUBLIC HEALTH SERVICE DEFINITION OF PERSONS WHO SHOULD REFRAIN FROM DONATING BLOOD AND PLASMA-UNITED STATES published in MMWR, September 6, 1985, pertains to potential donors who are at risk of having AIDS and should not donate blood or plasma (or other body tissues or fluids). This applies to men who may have had only one sexual contact with another man since 1977 and feel themselves neither homosexual nor bisexual. (MMWR, September 6, 1985; Appendix V.)

F. REVISION OF THE CASE DEFINITION OF ACQUIRED IMMUNODEFICIENCY SYNDROME FOR NATIONAL REPORTING--UNITED STATES appeared in MMWR, June 28, 1985, and is a specific AIDS case definition used for epidemiologic purposes. (MMWR, June 28, 1985; Appendix VI.)

G. RECOMMENDATIONS FOR PREVENTING TRANSMISSION OF INFECTION WITH HUMAN T-LYMPHOTROPIC VIRUS TYPE III/LYMPHADENOPATHY-ASSOCIATED VIRUS DURING INVASIVE PROCEDURES appeared in MMWR, April 11, 1986, and addresses recommendations applicable to individuals who perform or assist in invasive procedures. (MMWR, April 11, 1986; Appendix VII)

H. RECOMMENDED INFECTION-CONTROL PRACTICES FOR DENTISTRY was published in MMWR, April 18, 1986 and addresses recommendations for dental personnel. (MMWR, April 18, 1986; Appendix VIII)

I. SAFETY OF THERAPEUTIC IMMUNE GLOBULIN PREPARATIONS WITH RESPECT TO TRANSMISSION OF HUMAN T-LYMPHOTROPIC VIRUS TYPE III/LYMPHADENOPATHY-ASSOCIATED VIRUS INFECTION appeared in MMWR, April 11, 1986 and addresses the safety of use of immune globulin (IG), hepatitis B immune globulin (HBIG) and intravenous immune globulin (IVIG). (MMWR, April 11, 1986; Appendix IX)

PERSONNEL POLICY

Existing state personnel laws, rules and policies regarding employment, working conditions, dismissal, sick leave, termination of employment and related matters shall apply to individuals diagnosed as having AIDS on the same basis as for persons having other diseases or conditions which may incapacitate them for work or otherwise affect job performance. [Refer to 1 CSR 20-3.070(2), 1 CSR 20-5.020(2), Section 36.180.3 RSMo, Section 36.380 RSMo and Section 104.515.3 RSMo]

CASE IDENTIFICATION

A. The legal and financial ramifications of a positive antibody test result have yet to be determined. Therefore care should be taken in determining persons to be screened. Mass or routine screening is not recommended. (The possibility of a false positive antibody test increases in low risk populations.) Exceptions may include high risk or symptomatic individuals (as determined by social, medical history) in environments conducive to HTLV-III transmission. (e.g., those where person to person transfer of blood and/or semen may occur in a sexual or drug-related setting.)

B. Individuals testing positive for HTLV-III antibodies will be directed to trained counselors. (See Appendix XI; This appendix provides the list of alternate testing sites to which Missouri citizens may go to be tested and counseled regarding HTLV-III antibody. The Appendix also includes the list of mental health centers to which the alternative sites may refer individuals for additional supportive mental health counseling.)

C. Individuals diagnosed as having AIDS will be directed to trained counselors and/or local self-help AIDS crisis organizations. Information about medical, financial and referral assistance will be provided to the individual when applicable to the person's needs.

D. Individuals who fit the criteria for "high-risk" groups as previously defined should be encouraged to seek evaluation by their physician every six months for the clinical symptoms and signs related to AIDS.

E. All information, or transfer of information, pertaining to infected persons or AIDS patients will be handled in a confidential manner consistent with applicable law.

CONTROL MEASURES:

The control measures listed are applicable to those individuals who are diagnosed as having AIDS or who have been found serologically positive for HTLV-III.

A. All blood and body fluid spills should be cleaned promptly with a disinfectant solution (e.g., household bleach-hypochlorite---at 1:10 dilution with water or an EPA approved hospital disinfectant). See pg. 14 third paragraph.

B. Resuscitation apparatus (bags, mouth pieces or ventilation devices) should be available anywhere there may be a need for emergency mouth-to-mouth resuscitation. CPR - Portable cardiopulmonary resuscitation equipment (e.g., a disposable AMBU bag and oral airway) or other emergency equipment designed to prevent direct contact should be available in all agencies.

C. Gloves should be worn and hands should be washed routinely when working in potentially invasive procedures with HTLV-III positive, ARC or AIDS patients. Hands should be washed immediately if accidentally contaminated with blood. In addition, eyes or open wounds exposed to blood or body fluids should be copiously flushed with water. Open wounds may also be flushed with a hydrogen peroxide solution if available.

D. After accidental exposure, medical evaluation should determine whether an HTLV-III serology test should be obtained. If tested, and the individual is found to be sero-negative, retest after six weeks and then at three, six and twelve months. Exposure to blood or other body fluids by needle-stick wound or mucosal contamination should be reported promptly to health care personnel for evaluation.

F. Blood/Body Fluids Precautions are indicated for all patients with AIDS, suspected AIDS or ARC or known HTLV-III positive serology. (See Appendix I.)

G. Non-disposable articles which are contaminated by blood or body fluid exposure should be handled as in accordance with the guidelines in Appendix I. All items should be clearly labeled and placed in protective containers.

H. Disposable syringes and needles or sharp objects that may serve as vehicles of transmission should be placed into puncture-resistant containers. To prevent needle-stick injuries, needles should not be recapped, bent, broken, removed from disposable syringes, or otherwise manipulated by hand.

I. Personnel who transport individuals with AIDS or HTLV-III antibody positive status should exercise blood/body precautions to reduce the risk of HTLV-III transmission. Other precautions to avoid the transmission of opportunistic and/or communicable diseases should be exercised as indicated.

REPORTING

AIDS is a reportable disease in the State of Missouri. (Appendix X - 13 CSR 50-101.020)

A P P E N D I X

APPENDIX I

Summary: Recommendations for Preventing Transmission of Infection with Human T-lymphotropic Virus Type III/Lymphadenopathy-Associated Virus in the Workplace

(Reprinted from MMWR, November 15, 1985)

The information and recommendations contained in this document have been developed with particular emphasis on health-care workers and others in related occupations in which exposure might occur to blood from persons infected with HTLV-III/LAV, the "AIDS virus." Because of public concern about the purported risk of transmission of HTLV-III/LAV by persons providing personnel services and those preparing and serving food and beverages, this document also addressess personal-service and food-service workers. Finally, it addresses "other-workers"-persons in settings, such as offices, schools, factories, and construction sites, where there is no known risk of AIDS virus transmission.

Because AIDS is a bloodborne, sexually transmitted disease that is not spread by casual contact, this document does not recommend routine HTLV-III/LAV antibody screening for the groups addressed. Because AIDS is not transmitted through preparation or serving of food and beverages, these recommendations state that food-service workers known to be infected with AIDS should not be restricted from work unless they have another infection or illness for which such restrictions would be warranted.

This document contains detailed recommendations for precautions appropriate to prevent transmission of all bloodborne infectious disease to people exposed--in the course of their duties--to blood from persons who may be infected with HTLV-III/LAV. They emphasize that health-care workers should take all possible precautions to prevent needlestick injury. The recommendations are based on the well-documented modes of HTLV-III/LAV transmission and incorporate a "worst case" scenario, the hepatitis B model of transmission. Because the hepatitis B virus is also bloodborne and is both hardier and more infectious than HTLV-III/LAV, recommendations that would prevent transmission of hepatitis B will also prevent transmission of AIDS.

Formulation of specific recommendations for health-care workers who perform invasive procedures is in progress.

Persons at increased risk of acquiring infection with human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV), the virus that causes acquired immunodeficiency syndrome (AIDS), include homosexual and bisexual men, intravenous (IV) drug abusers, persons transfused with contaminated blood or blood products, heterosexual contacts of persons with HTLV-III/LAV infection, and children born to infected mothers. HTLV-III/LAV is transmitted through sexual contact, parenteral exposure to infected blood or blood components, and perinatal transmission from mother to neonate. HTLV-III/LAV has been isolated from blood, semen, saliva, tears, breast milk, and urine and is likely to be isolated from some other body fluids, secretions, and excretions, but epidemiologic evidence has

implicated only blood and semen in transmission. Studies of nonsexual household contacts of AIDS patients indicate that casual contact with saliva and tears does not result in transmission of infection. Spread of infection to household contacts of infected persons has not been detected when the household contacts have not been sex partners or have not been infants of infected mothers. The kind of nonsexual person-to-person contact that generally occurs among workers and clients or consumers in the workplace does not pose a risk for transmission of HTLV-III/LAV.

As in the development of any such recommendations, the paramount consideration is the protection of the public's health. The following recommendations have been developed for all workers, particularly workers in occupations in which exposure might occur to blood from individuals infected with HTLV-III/LAV. These recommendations reinforce and supplement the specific recommendations that were published earlier for clinical and laboratory staffs (1) and for dental-care personnel and persons performing necropsies and morticians' services (2) Because of public concern about the purported risk of transmission of HTLV-III/LAV by persons providing personal services and by food and beverages, these recommendations contain information and recommendations for personal-service and food-service workers. Finally, these recommendations address workplaces in general where there is no known risk of transmission of HTLV-III/LAV (e.g., offices, schools, factories, construction sites). Formulation of specific recommendations for health-care workers (HCW's) who perform invasive procedures (e.g., surgeons, dentists) is in progress. Separate recommendations are also being developed to prevent HTLV-III/LAV transmission in prisons, other correctional facilities, and institutions housing individuals who may exhibit uncontrollable behavior (e.g., custodial institutions) and in the perinatal setting. In addition, separate recommendations have already been developed for children in schools and day-care centers (3).

HTLV-III/LAV-infected individuals include those with AIDS (4); those diagnosed by their physician(s) as having other illnesses due to infection with HTLV-III/LAV; and those who have virologic or serologic evidence of infection with HTLV-III/LAV but who are not ill.

These recommendations are based on the well-documented modes of HTLV-III/LAV transmission identified in epidemiologic studies and on comparison with the hepatitis B experience. Other recommendations are based on the hepatitis B model of transmission.

COMPARISONS WITH THE HEPATITIS B VIRUS EXPERIENCE

The epidemiology of HTLV-III/LAV infection is similar to that of Hepatitis B virus (HBV) infection, and much that has been learned over the last 15 years related to the risk of acquiring hepatitis B in the workplace can be applied to understanding the risk of HTLV-III/LAV transmission in the health-care and other occupational settings. Both viruses are transmitted through sexual contact, parenteral exposure to contaminated blood or blood products, and perinatal transmission from infected mothers to their offspring. Thus, some of the same major groups at high risk for HBV infection (e.g., homosexual men, IV drug abusers, persons with hemophilia, infants born to infected mothers) are

also the groups at highest risk for HTLV-III/LAV infection. Neither HBV nor HTLV-III/LAV has been shown to be transmitted by casual contact in the workplace, contaminated food or water, or airborne or fecal-oral routes (5).

HBV infection is an occupational risk for HCW's, but this risk is related to degree of contact with blood or contaminated needles. HCW's who do not have contact with blood or needles contaminated with blood are not at risk for acquiring HBV infection in the workplace (6-8).

In the health-care setting, HBV transmission has not been documented between hospitalized patients, except in hemodialysis units, where blood contamination of the environment has been extensive or where HBV-positive blood from one patient has been transferred to another patient through contamination of instruments. Evidence of HBV transmission from HCW's to patients has been rare and limited to situations in which the HCW's exhibited high concentration of virus in their blood (at least 1,000,000 infectious virus particles per ml of serum), and the HCW's sustained a puncture wound while performing traumatic procedures on patients or had exudative or weeping lesions that allowed virus to contaminate instruments or open wounds of patients (9-11).

Current evidence indicates that, despite epidemiologic similarities of HBV and HTLV-III/LAV infection, the risk for HBV transmission in health-care settings far exceeds that for HTLV-III/LAV transmission. The risk of acquiring HBV infection following a needlestick from an HBV carrier ranges from 6% to 30% (12, 13), far in excess of the risk of HTLV-III/LAV infection following a needlestick involving a source patient infected with HTLV-III/LAV, which is less than 1%. In addition, all HCW's who have been shown to transmit HBV infection in health care settings have belonged to the subset of chronic HBV carriers who, when tested have exhibited evidence of exceptionally high concentrations of virus (at least 1,000,000 infectious virus particles per ml) in their blood. Chronic carriers who have substantially lower concentrations of virus in their blood have not been implicated in transmission in the health-care setting (9-11, 14). The HBV model thus represents a "word-case" condition in regard to transmission in health-care and other related settings. Therefore, recommendations for the control of HBV infection should, if followed, also effectively prevent spread of HTLV-III/LAV. Whether additional measures are indicated for those HCW's who perform invasive procedures will be addressed in the recommendations currently being developed.

Routine screening of all patients or HCW's for evidence of HBV infection has never been recommended. Control of HBV transmission in the health-care setting has emphasized the implementation of recommendations for the appropriate handling of blood, other body fluids, and items soiled with blood or other body fluids.

TRANSMISSION FROM PATIENTS TO HEALTH CARE WORKERS

HCW's include, but are not limited to, nurses, chiropractors, laboratory and blood bank technologists and technicians, phlebotomists, dialysis personnel, paramedics, emergency medical technicians, medical examiners, morticians, housekeepers, laundry workers, and others whose

work involves contact with patients, their blood or other blood fluids, or corpses.

Recommendations for HCW's emphasize precautions appropriate for preventing transmission of bloodborne infectious disease, including HTLV-III/LAV and HBV infection.

Risk of HCW's acquiring HTLV-III/LAV in the workplace. Using the HBV model, the highest risk for transmission of HTLV-III/LAV in the workplace would involve parenteral exposure to a needle or other sharp instrument contaminated with blood of an infected patient. The risk to HCW's of acquiring HTLV-III/LAV infection in the workplace has been evaluated in several studies. In five separate studies, a total of 1,498 HCW's have been tested for antibody to HTLV-III/LAV. In these studies, 666 (44.5%) of the HCW's had direct parenteral (needlestick or cut) or mucuos membrane exposure to patients with AIDS or HTLV-III/LAV infection. Most of these exposures were to blood rather than to other body fluids. None of the HCW's whose initial serologic tests were negative developed subsequent evidence of HTLV-III/LAV infection following their exposures. Twenty-six HCW's in these five studies were seropositive when first tested, all but three of these persons belonged to groups recognized to be at increased risk for AIDS (15). Since one was tested anonymously, epidemiologic information was available on only two of these three seropositive HCW's. Although these two HCW's were reported as probable occupationally-related HTLV-III/LAV infection (15, 16), neither had a pre-exposure nor an early postexposure serum sample available to help determine the onset of infection. One case reported from England describes a nurse who seroconvented following an accidental parenteral exposure to a needle contaminated with blood from an AIDS patient (17).

In spite of the extremely low risk of transmission of HTLV-III/LAV infection, even when needlestick injuries occur, more emphasis must be given to precautions targeted to prevent needlestick injuries in HCW's caring for any patient, since such injuries continue to occur even during the care of patients who are known to be infected with HTLV-III/LAV.

Precautions to prevent acquisition of HTLV-III/LAV infection by HCW's in the workplace. These precautions represent prudent practices that apply to preventing transmission of HTLV-III/LAV and other bloodborne infections and should be used routinely (18).

1. Sharp items (needles, scalpel blades, and other sharp instruments) should be considered as potentially infective and be handled with extraordinary care to prevent accidental injuries.
2. Disposable syringes and needles, scalpel blades, and other sharp instruments should be placed into puncture-resistant containers located as close as practical to the areas in which they were used. To prevent needlestick injuries, needles should not be recapped, purposefully bent, broken, removed from disposable syringes, or otherwise manipulated by hand.
3. When the possibility of exposure to blood or other body fluids exists routinely recommended precautions should be followed.

The anticipated exposure may require gloves alone, as in handling items soiled with blood or equipment contaminated with blood or other body fluids, or may also require gowns, masks, and eye-coverings when performing procedures involving more extensive contact with blood or potentially infective body fluids, as in some dental or endoscopic procedures or postmortem examinations. Hands should be washed thoroughly and immediately if they accidentally become contaminated with blood.

4. To minimize the need for emergency mouth-to-mouth resuscitation, mouth pieces, resuscitation bags, or other ventilation devices should be strategically located and available for use in areas where the need for resuscitation is predictable.
5. Pregnant HCW's are not known to be at greater risk of contracting HTLV-III/LAV infections than HCW's who are not pregnant; however, if a HCW develops HTLV-III/LAV infection during pregnancy, the infant is at increased risk of infection resulting from perinatal transmission. Because of this risk, pregnant HCW's should be especially familiar with precautions for preventing HTLV-III/LAV transmission (19).

Precautions for HCW's during home care of persons infected with HTLV-III/LAV. Persons infected with HTLV-III/LAV can be safely cared for in home environments. Studies of family members of patients infected with HTLV-III/LAV have found no evidence of HTLV-III/LAV transmission to adults who were not sexual contacts of the infected patients or to children who were at no risk for perinatal transmission (3). HCW's providing home care face the same risk of transmission of infection as HCW's in hospitals and other health care settings, especially if there are needlesticks or other parenteral or mucous membrane exposures to blood or other body fluids.

When providing health-care service in the home to persons infected with HTLV-III/LAV, measures similar to those used in hospitals are appropriate. As in the hospital, needles should not be recapped, purposefully bent, broken, removed from disposable syringes, or otherwise manipulated by hand. Needles and other sharp items should be placed into puncture-resistant containers and disposed of in accordance with local regulations for solid waste. Blood and other body fluids can be flushed down the toilet. Other items for disposal that are contaminated with blood or other body fluids that cannot be flushed down the toilet should be wrapped securely in a plastic bag that is impervious and sturdy (not easily penetrated).

It should be placed in a second bag before being discarded in a manner consistent with local regulations for solid waste disposal. Spills of blood or other body fluids should be cleaned with soap and water or a household detergent. As in the hospital, individuals cleaning up such spills should wear disposable gloves. A disinfectant solution or a freshly prepared solution of sodium hypochlorite (household bleach, see above) should be used to wipe the area after cleaning.

Precautions for providers of prehospital emergency health care. Providers of prehospital emergency health care include the following:

paramedics, emergency medical technicians, law enforcement personnel, firefighters, lifeguards, and others whose job might require them to provide first-response medical care. The risk of transmission of infection including, HTLV-III/LAV infection, from infected persons to providers of prehospital emergency health care should be no higher than that for HCW's providing emergency care in the hospital appropriate precautions are taken to prevent exposure to blood or other body fluids.

Providers of prehospital emergency health care should follow the precautions outlined above for other HCW's. No transmission of HBV infection during mouth-to-mouth resusotation has been documented. However, because of the theuretical risk of salivary transmission of HTLV-III/LAV during mouth-to-mouth resuscitation bags and the wearing of gloves when in contact with blood and or other body fluids. Resuscitation equipment and devices known or suspected to be contaminated with blood or other body fluids should be used once and disposed of or be thoroughly cleaned and disinfected after each use.

Management of parenteral and mucous membrane exposure of HCW's. If a HCW has a parenteral (e.g. needlestick or cut) or mucous membrane (e.g. splash to the eye or mouth) exposure to blood or other body fluids, the source patient should be assessed clinically and epidemiologically to determine the likelihood of HTLV-III infection. It the assessment suggests that infection may exist, the patient should be informed of the incident and requested to consent to serologic testing for evidence of HTLV-III/LAV infection. If the source patient has AIDS or other evidence of HTLV-III/LAV infection, declines testing, or has a positive test, the HCW should be evaluated clinically and serologically for evidence of HTLV-III/LAV infection as soon as possible after the exposure and, if seronegative, retested after 6 weeks and on a periodic basis (e.g. 3, 6, and 12 months following exposure) to determine if transmission has occured. During this follow-up period, especially the first 6-12 weeks, when most infected persons are expected to seroconvert, exposed HCW's should receive counseling about the risk of infection and follow U.S. Public Health Service (PHS) recommendations for preventing transmission of AIDS (20, 21). If the source patient is seronegative and has no other evidence of HTLV-III/LAV infection, no further follow-up of the HCW is necessary. If the source patient cannot be identified, decisions regarding appropriate follow-up should be individualized based on the type of exposures and the likelihood that the source patient was infected.

Serologic testing of patients. Routine serologic testing of all patients for antibody to HTLV-III/LAV is not recommended to prevent transmission of HTLV-III/LAV infection in the workplace. Results of such testing are unlikely to further reduce the risk of transmission, which, even with documented needlesticks, is already low. Furthermore, the risk of needlestick and other parenteral exposures could be reduced by emphasizing and more consistently implementing routinely recommended infection-control precautions (e.g. not recapping needles). Moreover, results of routine serologic testing would not be available for emergency cases and patients with short lengths of stay, and additional tests to determine whether a positive test was a true

or false positive would be required in populations with a low prevalence of infection. However, this recommendation is based only on considerations of occupational risks and should not be construed as a recommendation against other uses of the serologic test, such as for diagnosis or to faciliate medical management of patients. Since the experience with infected patients varies substantially among hospitals (75% of all AIDS cases have been reported by only 280 of the more than 6,000 acute care hospitals in the United States), some hospitals in certain geographic areas may deem it appropriate to initiate serologic testing of patients.

TRANSMISSION FROM HEALTH-CARE WORKERS TO PATIENTS

Risk of transmission of HTLV-III/LAV infection from HCW's to patients. Although there is no evidence that HCW's infected with HTLV-III/LAV have transmitted infection to parients, a risk of transmission of HTLV-III/LAV infection from HCW's to patients would exist in situations where there is both (1) a high degree of trauma to the patient that would provide a potential entry for the virus (e.g. during invasive procedures) and (2) access of blood or serous fluid from the infected HCW to the open tissue of a patient, as could occur if the HCW sustains a needlestick or scalpel injury during an invasive procedure. HCW's known to be infected with HTLV-III/LAV who do not perform invasive procedures need not be restricted from work unless they have evidence of other infection or illness for which any HCW should be restricted. Whether additional restrictions are indicated for HCW's who perform invasive procedures is currently being considered.

Precautions to prevent transmission of HTLV-III/LAV infection from HCW's to patients. These precautions apply to all HCW's, regardless of whether they perform invasive procedures: (1) All HCW's should wear gloves for direct contact with mucous membranes or nonintact skin of all patients and (2) HCW's who have exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient-care equipment until the condition resolves.

Management of parenteral and mucous membrane exposures of patients. If a patient has a parenteral or mucous membrane exposure to blood or other body fluids of a HCW, the patient should be informed of the incident and the same procedure outlined above for exposures of HCW's to patients should be followed for both the source HCW and the potentially exposed patient. Management of this type of exposure will be addressed in more detail in the recommendations for HCW's who perform invasive procedures.

Serologic testing of HCW's. Routine serologic testing of HCW's who do not perform invasive procedures (including providers of home and prehospital emergency care) is not recommended to prevent transmission of HTLV-III/LAV infection. The risk of transmission is extremely low and can be further minimized when routinely recommended infection-control precautions are followed. However, serologic testing should be available to HCW's who may wish to know their HTLV-III/LAV infection status. Whether indications exist for serologic

testing of HCW's who perform invasive procedures is currently being considered.

Risk of occupational acquisition of other infectious diseases by HCW's infected with HTLV-III/LAV. HCW's who are known to be infected with HTLV-III/LAV and who have definite immune systems are at increased risk of acquiring of experiencing serious complications of other infectious diseases. Of particular concern is the risk of severe infection following exposure to patients with infectious diseases that are easily transmitted if appropriate precautions are not taken (e.g. tuberculosis). HCW's infected with HTLV-III/LAV should be counseled about the potential risk associated with taking care of patients with transmissible infections and should continue to follow existing recommendations for infection control to minimize their risk of exposure to other infectious agents (18, 19). The HCW's personal physician(s), in conjunction with their institutions' personnel health services or medical directors, should determine on an individual basis whether the infected HCW's can adequately and safely perform patient care duties and suggest changes in work assignments, if indicated. In making this determination, recommendations of the Immunization Practices Advisory Committee and institutional policies concerning requirements for vaccinating HCW's with live-virus vaccines should also be considered.

STERILIZATION, DISINFECTION, HOUSEKEEPING, AND WASTE DISPOSAL TO PREVENT TRANSMISSION OF HTLV-III/LAV

Sterilization and disinfection procedures currently recommended for use (22,23) in health-care and dental facilities are adequate to sterilize or disinfect instruments, devices, or other items contaminated with the blood or other body fluids from individuals infected with HTLV-III/LAV. Instruments or other nondisposable items that enter normally sterile tissue or the vascular system or through which blood flows should be sterilized before reuse. Surgical instruments used on all patients should be decontaminated after use rather than just rinsed with water. Decontamination can be accomplished by machine or by hand cleaning by trained personnel wearing appropriate protective attire (24) and using appropriate chemical germicides. Instruments or other nondisposable items that touch intact mucous membranes should receive high level disinfection.

Several liquid chemical germicides commonly used in laboratories and health-care facilities have been shown to kill HTLV-III/LAV at concentrations much lower than are used in practice (25). When decontaminating instruments or medical devices, chemcial germicides that are registered with and approved by the U.S. Environmental Protection Agency (EPA) as "sterilants" can be used either for sterilization or for high-level disinfection depending on contact time; germicides that are approved for use as "hospital disinfectants" and are mycobactericidal when used in appropriate dilutions can also be used for high-level disinfection of devices and instruments. Germidicides that are mycobactericidal are preferred because mycobacteria represent one of the most resistant groups of microorganisms; therefore, germicides that are effective against mycobacteria are also effective against other bacterial and viral pathogens. When chemical germicides are used, instruments or devices

to be sterilized or disinfected should be thoroughly cleaned before exposure to the germicide, and the manufacturer's instructions for use of the germicide should be followed.

Laundry and dishwashing cycles commonly used in hospitals are adequate to decontaminate linens, dishes, glassware, and utensils. When cleaning environmental surfaces, housekeeping procedures commonly used in hospitals are adequate; surfaces exposed to blood and body fluids should be cleaned with a detergent followed by decontamination using an EPA-approved hospital disinfectant that is mycobactericidal. Individuals cleaning up such spills should wear disposable gloves. Information on specific label claims of commercial germicides can be obtained by writing to the Disinfectants Branch, Office of Pesticides, Environmental Protection AGency, 401 M Street, S.W., Washington, D.C., 20460.

In addition to hospital disinfectants, a freshly prepared solution of sodium hypochlorite (household bleach) is an inexpensive and very effective germicide (25). Concentrations ranging for 5,000 ppm (a 1:10 dilution of household bleach) to 500 ppm (a 1:100 dilution) sodium hypochlorite are effective, depending on the amount of organic material (e.g. blood, mucus, etc.) present on the surface to be cleaned and disinfected.

Sharp items should be considered as potentially infective and should be handled and disposed of with extraordinary care to prevent accidental injuries. Other potentially infective waste should be contained and transported in clearly identified impervious plastic bags. If the outside of the bag is contaminated with blood or other body fluids, a second outer bag should be used. Recommended practices for disposal of infective waste (23) are adequate for disposal of waste contaminated by HTLV-III/LAV. Blood and other body fluids may be carefully poured down a drain connected to a sanitary sewer.

CONSIDERATIONS RELEVANT TO OTHER WORKERS

Personal-service workers (PSWs). PSWs are defined as individuals whose occupations involve close personal contact with clients (e.g., hairdressers, barbers, estheticians, cosmetologists, manicurists, pedicurists, massage therapists). PSWs whose services (tattooing, ear piercing, acupuncture, etc.) require needles or other instruments that penetrate the skin should follow precautions indicated for HCWs. Although there is no evidence of transmission of HTLV-III/LAV from clients to PSWs, from PSWs to clients, or between clients of PSWs, a risk of transmission would exist from PSWs to clients and vice versa in situations where there is both (1) trauma to one of the individuals that would provide a portal of entry for the virus and (2) access of blood or serous fluid from one infected person to the open tissue of the other, as could occur if either sustained a cut. A risk of transmission from client to client exists when instruments contaminated with blood are not sterilized or disinfected between clients. However, HBV transmission has been documented only rarely in acupuncture, ear piercing, and tattoo establishments and never in other personal-service settings, indicating that any risk for HTLV-III/LAV transmission in personal-service setting must be extremely low.

All PSWs should be educated about transmission of bloodborne infections, including HTLV-III/LAV and HBV. Such education should emphasize principles of good hygiene, antisepsis, and disinfection. This education can be accomplished by national or state professional organizations, with assistance from state and local health departments, using lectures at meetings or self-instructional materials. Licensure requirements should include evidence of such education. Instruments that are intended to penetrate theskin (e.g., tattooing and acupuncture needles, ear piercing devices) should be used once and disposed of or be thoroughly cleaned and sterilized after each use using procedures recommended for use in health-care institutions. Instruments not intended to penetrate the skin but which may become contaminated with blood (e.g., razors), should be used for only one client and be disposed of or thoroughly cleaned and disinfected after use using procedures recommended for use in health-care institutions. Any PSW with exudative lesions or weeping dermatitis, regardless of HTLV-III/LAV infection status, should refrain from direct contact with clients until the condition resolves. PSWs known to be infected with HTLV-III/LAV need not be restricted from work unless they have evidence of other infections or illnesses for which any PSW should also be restricted.

Routine serologic testing of PSWs for antibody to HTLV-III/LAV is not recommended to prevent transmission from PSWs to clients.

Food-service workers (FSWs). FSWs are defined as individuals whose occupations involve the preparation or serving of food or beverages (e.g., cooks, caterers, servers, waiters, bartenders, airline attendants). All epidemiologic and laboratory evidence indicates that bloodborne and sexually transmitted infections are not transmitted during the preparation or serving of food or beverages, and no instances of HBV or HTLV-III/LAV transmission have been documented in this setting.

All FSWs should follow recommended standards and practices of good personal hygiene and food sanitation (26). All FSWs should exercise care to avoid injury to hands when preparing food. Should such an injury occur, both aesthetic and sanitary considerations would dictate that food contaminated with blood be discarded. FSWs known to be infected with HTLV-III/LAV need not be restricted from work unless they have evidence of other infection or illness for which any FSW should also be restricted.

Routine serologic testing of FSWs for antibody to HTLV-III/LAV is not recommended to prevent disease transmission from FSWs to consumers.

Other workers sharing the same work environment. No known risk of transmission to co-workers, clients, or consumers exists from HTLV-III/LAV-infected workers in other settings (e.g., offices, schools, factories, construction sites). This infection is spread by sexual contact with infected persons, injection of contaminated blood or blood products, and by perinatal transmission. Workers known to be infected with HTLV-III/LAV should not be restricted from work solely

based on this finding. Moreover, they should not be restricted from using telephone, office equiment, toilets, showers, eating facilities, and water fountains. Equipment contaminated with blood or other body fluids of any worker, regardless of HTLV-III/LAV infection status, should be cleaned with soap and water or a detergent. A disinfection solution or a fresh solution of sodium hypochlorite (household bleach, see above) should be used to wipe the area after cleaning.

OTHER ISSUES IN THE WORKPLACE

The information and recommendations contained in this document do not address all the potential issues that may have to be considered when making specific employment decisions for persons with HTLV-III/LAV infection. The diagnosis of HTLV-III/LAV infection may evoke unwarranted fear and suspicion in some co-workers. Other issues that may be considered include the need for confidentiality, applicable federal, state, or local laws governing occupational safety and health, civil rights of employees, workers' compensation laws, provisions of collective bargaining agreements, confidentiality of medical records, informed consent, employee and patient privacy rights, and employee right-to-know statutes.

DEVELOPMENT OF THESE RECOMMENDATIONS

The information and recommendations contained in these recommendations were developed and compiled by CDC and other PHS agencies in consultation with individuals representing various organizations. The following organizations were represented: Association of State and Territorial Health Officials, Conference of State and Territorial Epidemiologists, Association of State and Territorial Public Health Laboratory Directors, National Association of County Health Officials, American Hospital Association, United States Conference of Local Health Officers, Association for Practitioners in Infection Control, Society of Hospital Epidemiologist of America, American Dental Association, American Medical Association, American Nurses' Association, American Dental Association, American Medical Association, American Dental Schools, National Institutes of Health, Food and Drug Administration, Food Research Institute, National Restaurant Association, National Hairdressers and Cosmetologist Association, National Gay Task Force, National Funeral Directors and Morticians Association, American Association of Physicians for Human Rights, and National Association of Emergency Medical Technicians. The consultants also included a labor union representative, an attorney, a corporate medical director, and a pathologist. However, these recommendations may not reflect the views of individual consultants or the organizations they represented.

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APPENDIX II

Recommendations for Assisting in the Prevention of Perinatal Transmission of Human T-Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus and Acquired Immunodeficiency Syndrome (Reprinted from MMWR, December 6, 1985)

The information and recommendations in this document are intended to assist health-care providers and state and local health departments in developing procedures to prevent perinatal transmission of human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III LAV), the virus that causes acquired immunodeficiency syndrome (AIDS).

This document contains recommendations for providing counselling and, when indicate, testing for antibody to HTLV-III/LAV for women who are at increased risk of acquiring the virus and who are either pregnant or may become pregnant. It is important that these women know they are at risk, as well as know and understand their HTLV-III/LAV-antibody status, so they can make informed decisions to help prevent perinatally acquired HTLV-III/LAV-antibody status, so they can make informed decisions to help prevent perinatally acquired HTLV-III/LAV.

Through counselling, uninfected women can learn how to avoid becoming infected women can choose to delay pregnancy until more is known about perinatal transmission of the virus. If already pregnant, infected women can be provided information for managing the pregnancy and caring for the child.

Currently available data indicate that most pediatric HTLV-III/LAV infections and AIDS are acquired perinatally from infected women, but additional studies are needed to better quantify the risk of transmission from an infected pregnant woman to the fetus or newborn.

The recommendations below pertain to women. However, men who are HTLV-III/LAV-antibody positive should also be counselled regarding the risks of sexual and perinatal transmission, so they can refer for counselling and testing their sex partners who may be pregnant or considering pregnancy.

BACKGROUND

Pediatric AIDS Cases due to Perinatal Transmission. As of December 1, 1985, 217 (1%) of the 15,172 AIDS cases reported to CDC occurred among children under 13 years of age. Sixty percent of these children are known to have died. These 217 cases represent only the more severe manifestations of HTLV-III/LAV infection. Less severe manifestations, often described as AIDS-related complex (ARC), are not reported to CDC, so the number of children with clinically significant illness attributable to HTLV-III/LAV infection is greater than the

reported cases of pediatric AIDS. In addition, a number of infected children are probably asymptomatic.

Of the 217 reported pediatric AIDS patients, 165 (76%) have as their only known risk factor a mother belonging to a group with increased prevalence of HTLV-III/LAV infection. An additional 18% of the pediatric cases are attributable to transfusions of blood or blood products, while risk factor information is missing or incomplete on the remaining 6%. Of the 217 children with AIDS, 48% had mothers who were intravenous (IV) drug abusers; 17% had mothers who were born in Haiti; and 10% had mothers who were sex partners of either IV drug abusers or bisexual men.

Of the patients with perinatally acquired AIDS, 45% resided in New York City, while Florida and New Jersey accounted for an additional 32%.

Mechanisms of Perinatal Transmission. It is believed that HTLV-III/LAV is transmitted from infected women to their fetuses or offspring during pregnancy, during labor and delivery, or perhaps shortly after birth. Transmission of the virus during pregnancy or labor and delivery is demonstrated by two reported AIDS cases occurring in children who had no contact with their infected mothers after birth. One was delivered by Cesarean section (1,2).

Transmission of the virus after birth has been implicated in one case of HTLV-III/LAV infection in a child born to a mother reported to have acquired the infection from a postpartum blood transfusion. Since she breasted the child for 6 weeks, the authors suggested breastfeeding as the possible mode of transmission (3). Recently, HTLV-III/LAV has been isolated from the breast milk of infected women (4).

Risk of Perinatal Transmission from Infected Mothers. The rate of perinatal transmission of HTLV-III/LAV from infected pregnant women is unknown; however, available data suggest a high rate. In one study of 20 infants born to infected mothers who had already delivered on infant with AIDS, 13 (65%) had serologic and/or clinical evidence of infection with HTLV-III/LAV several months after birth (5,6). Since these women were selected on the basis of having previously transmitted HTLV-III/LAV perinatally, this study may overestimate the average risk of transmission for all infected pregnant women.

Perinatal transmission from an infected mother to her newborn is not inevitable. Of three children born to women who became infected with HTLV-III/LAV by artificial insemination from an infected donor, all were in good health and negative for antibody to the virus more than 1 year after birth (7). Another child, born to a woman who was already pregnant at the time of AIDS diagnosis and was demonstrated to be viremic, was seronegative, culture negative, and healthy at birth and at 4 months of age (8). In a retrospective study evaluating nine children under 5 years of age whose mother were later diagnosed with AIDS, two (22%) had antibody to HTLV-III/LAV (9). The infection status of these women during pregnancy was unknown.

In these studies, the rate of transmission ranged from 0% (0/3) to 65% (13/20). Additional studies are needed to better define the rate of transmission and variables associated with it.

Risk of Illness among Infected Pregnant Women. Pregnancy is associated with suppression of cell-mediated immunity and increased susceptibility to some infections (10). The T-helper to T-suppressor ratio is decreased during normal pregnancy, being lowest in the third trimester, and returns to normal approximately 3 months postpartum (10). It is not known whether pregnancy increases an infected woman's risk of developing AIDS or ARC, but one study suggests it does (6). Fifteen infected women who were well at time of delivery were followed an average of 30 months after the births of their children. Five (33%) subsequently developed AIDS; seven (47%) developed AIDS-related conditions; and only three (20%) remained asymptomatic. These results may not apply to all infected pregnant women, but they do suggest an increased likelihood of developing disease when an HTLV-III/LAV infection occurs in association with pregnancy.

Prevalence of HTLV-III/LAV Infection. Counselling and testing for antibody to HTLV-III/LAV, when indicated, to reduce perinatal transmission of AIDS will be most beneficial in populations of women with increased prevalence of the virus (Table 1). These include: women who where heterosexual transmission is thought to play a major role (11,12); women who have engaged in prostitution; and women who are or have been sex partners of men who abuse IV drugs, are bisexual, have hemophilia, were born in countries where heterosexual transmission is thought to play a major role (11,12), or have evidence of HTLV-III/LAV infection.

The prevalence of antibody to HTLV-III/LAV in U.S. populations of men and women ranges from less than 0.01% in female blood donors to as high as 74% in men with hemophilia (13-15). Among heterosexual IV drug abusers, the prevalence of HTLV-III/LAV infection ranges from 2% to 59% in various geographic areas (16,17). Seroprevalence among the heterosexual partners of persons at increased risk for AIDS varies from 10% in female partners of asymptomatic, seropositive hemophilia patients to 71% in the female partners of men with AIDS or ARC (18-20). Among prostitutes, the HTLV-III/LAV antibody prevalence varies from 5% to 40%, depending on geographic area, with most of the women with positive tests relating histories of IV drug abuse (21). Among female blood donors in Atlanta, Georgia, who denied belonging to high-risk groups, 0.01% had repeatedly reactive enzyme-linked immunosorbent assays (ELISAs) followed by reactive Western blot tests (15).

TABLE 1. Prevention of HTLV-III/LAV antibody in hete se sera
States estern

Populations	Location		ti- be h
Intravenous drug abusers (16,17)	New York City		
	NJ* <5 miles from NYC)204		
	NJ 5-10 miles from NYC	124	
	NJ >100 miles from NYC	55	2
	San Francisco	53	9
Persons with hemophilia (13,14)		234	7
Factor VIII concentrate recipients		36	3
Factor IX concentrate recipients		15	4
Cryoprecipitate only recipients			
Female prostitutes (21)	Seattle, Washington	92	
	Miami, Florida	25	4
Female sex partners of men with AIDS or ARC (two separate studies) (19,20)		7	7
		42	4
Female sex partners of men with asymptomatic HTLV-III/LAV infection (18)		21	1
Haitians (12)	New York City	97	
	Miami, Florida	129	
Female blood donors (15)	Atlanta, Georgia	28,354	00

*New Jersey
)New York City

Commercially available tests to detect antibody to HTLV-III/LAV are ELISAs using antigens derived from whole disrupted HTLV-III/LAV. When the ELISA is reactive on initial testing, it is standard procedure to repeat the test on the same specimen. Repeatedly reactive tests are highly sensitive and specific for antibody to HTLV-III/LAV. However, when the ELISA is used to screen populations in which the prevalence of infection is very low (such as blood donors or women not in high-risk group), the proportion of repeatedly reactive results that are falsely positive will be higher. For that reason, an additional test, such as a Western blot, is recommended following repeatedly reactive ELISA results, especially in low-prevalence populations. In populations with high prevalence of infection (e.g. homosexual men or IV drug abusers), most repeatedly reactive ELISAs are reactive by Western blot or another test. For example, among 109 IV drug abusers whose sera were repeatedly reactive by ELISA, over 85% were reactive by Western blot (22). In contrast,

in a low-prevalence population of 69 female blood donors whose sera were repeatedly reactive by ELISA, only 5% were reactive by Western blot (15).

Due to the seriousness of the implications of HTLV-III/LAV-antibody reactivity, it is recommended that repeatedly reactive ELISAs be followed by an additional test, such as the Western blot. Women with sera repeatedly reactive by ELISA and reactive by Western blot should have a thorough medical evaluation. HTLV-III/LAV has been isolated from a single specimen in 67%-95% of persons with specific antibody (23,24). Because infection has been demonstrated in a asymptomatic persons, the presence of specific antibody should be considered presumptive evidence of current infection and infectiousness.

RECOMMENDATIONS

Women Who Should be Offered Counselling and Testing. Counselling services and testing for antibody to HTLV-III/LAV should be offered to pregnant women and women who may become pregnant in the following groups: (1) those who have evidence of HTLV-III/LAV infection; (2) those who have used drugs intravenously for non-medical purposes; (3) those who were born in countries where heterosexual transmission is thought to play a major role (11,12); (4) those who have engaged in prostitution; (5) those who are or have been sex partners of: IV drug abusers, bisexual men, men with hemophilia, men who were born in countries where heterosexual transmission is thought to play a major role (11,12), or men who otherwise have evidence of HTLV-III/LAV infection. If data become available to show that HTLV-III/LAV-antibody prevalence is increased in other groups or settings, counselling and testing programs should be extended to include them. Routine counselling and testing of women who are not included in the above-mentioned groups is not recommended due to low prevalence of infection and concern about interpretation of test results in a low-prevalence population. However if a woman requests it, the service should be provided in accordance with these recommendations.

Settings for Offering Counselling and Testing. Counselling and testing for antibody to HTLV-III/LAV to prevent perinatal transmission is recommended in the setting of any medical service in which women at increased risk are commonly encountered. These include services for treating IV drug abuse (i.e., detoxification and methadone maintenance), comprehensive hemophilia treatment centers, sexually transmitted disease clinics, and clinics that serve female prostitutes. In addition, services related to reproduction, such as family planning and infertility services, gynecologic, premarital, or preconceptual examinations, and prenatal and obstetric services should also consider offering counselling and testing if high-risk women are seen at these facilities. Testing for antibody to HTLV-III/LAV should be performed with the woman's consent after counselling is provided regarding risk factors for infection, the interpretation of test results, the risks of transmission, and the possible increased likelihood of disease among women infected with HTLV-III/LAV in association with pregnancy. The counselling and testing must be conducted in an environment in which confidentiality can be assured. In settings where confidential counselling and testing cannot be

assured, information should be provided and referrals made to appropriate facilities.

Frequency of Testing. Detectable antibodies to HTLV-III/LAV may not develop until 2-4 months after exposure. This, and whether the woman is continuously exposed, should be taken into account when considering the need for, and frequency of, repeat testing. High-risk women should be offered counselling and testing should be offered as soon as the woman is known to be pregnant. If the initial test is negative, repeat testing may be indicated near delivery to aid in the clinical management of the pregnant woman and newborn. If this final test is negative and the mother's risk of exposure no longer exists, she may safely consider breastfeeding the child, and management of the child need not include the same concerns that would be appropriate if the woman had had a positive test or if she were at high risk and had not been tested at all.

Counselling Women with Positive Results. Women with virologic or serologic evidence of HTLV-III/LAV infection should be counselled regarding their own risk of AIDS and the risk of perinatal and sexual transmission of HTLV-III/LAV. Infected women should be counselled to refer their sex partners for counselling and testing. If the partners of these women are not infected, both members of the couple should be counselled on how they may modify their sexual practices to reduce the risk of HTLV-III/LAV transmission to the uninfected partner. In addition, the couple should be told not to donate blood, organs, or sperm and should be discouraged from using IV drugs and advised against sharing needles and syringes. When seeking medical or dental care for intercurrent illness, they should inform those responsible for their care of their positive antibody status so appropriate evaluation can be undertaken. Recommendations for providing information and advice to individuals infected with HTLV-III/LAV have been published (25).

Infected women should be advised to consider delaying pregnancy until more is known about perinatal transmission of the virus. Pregnant infected women may require additional medical and social support services due to an enhanced risk of opportunistic infections and psychosocial difficulties during and after pregnancy. Obstetric-care providers should be alert to signs an symptoms of HTLV-III/LAV and related opportunistic infections in these pregnant women and to the need for specialized medical care.

HTLV-III/LAV-infected women should be advised against breastfeeding to avoid postnatal transmission to a child who may not yet be infected. The child should receive follow-up pediatric evaluations to determine whether he/she has HTLV-III/LAV infection, and to diagnose and treat promptly any diseases that may be secondary to HTLV-III/LAV infection. Recommendations for educating and providing foster care for infected children have been published (26).

Counselling Women with Negative Test Results. A negative ELISA for HTLV-III/LAV antibody in women who have no clinical or laboratory evidence of HTLV-III/LAV infection is evidence that they have probably not been infected. However, uninfected women who have sex partners with evidence of HTLV-III/LAV infection or with an increased risk of

becoming infected should be informed that sexual intercourse increases their risk of infection. These women should be informed of the risks associated with pregnancy if they become infected and advised to consider delaying pregnancy until more is known about perinatal transmission of the virus or until they are no longer considered to be at risk for acquiring the virus. In addition to preventing pregnancy, the consistent and proper use of condoms can offer some protection against HTLV-III/LAV infection.

High-risk women, even if seronegative, should be told not to donate blood or organs. To decrease their risk of becoming infected, IV drug abusers should be encouraged to seek treatment for their drug abuse. Persons counselling IV drug abusers should know that IV drug abuse is often strongly ingrained and compulsive. Despite educational efforts and encouragement for treatment, some addicts will continue to abuse drugs or relapse after treatment. If drug abuse continues, they should be advised not to share needles or syringes and to use only sterile equipment.

Additional Considerations. These recommendations will be revised as additional information becomes available. It is recognized that provision of the recommended professional counselling, HTLV-III/LAV-antibody testing and associated specialized medical services will take time to implement and may stress available resources, particularly in public facilities, which are most greatly affected. Health-care providers, social-service personnel, and others involved in educating and caring for HTLV-III/LAV-infected persons should be aware of the potential for social isolation and should be sensitive to the need for confidentiality. They should be familiar with federal and state laws, regulations, and policies that protect the confidentiality of clinical data and test results. Each institution should assure that specific mechanisms are in place to protect the confidentiality of all records and to prevent the misuse of information. Anonymous testing would not be appropriate if it prevents adequate counselling and medical follow-up evaluation.

Hospital precautions for managing infected women and infants should be patterned after those for caring for patients with HTLV-III/LAV infection (27,28). Additional recommendations will follow.

DEVELOPMENT OF THESE RECOMMENDATIONS

The information and recommendations contained in this document were developed and compiled by CDC and the U.S. Public Health Service in consultation with individuals representing: the Conference of State and Territorial Epidemiologists, the Association of State and Territorial Health Officials, the American Public Health Association, the United States Conference of Local Health Officers, the American Medical Association, the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, the Planned Parenthood Federation of America, the American Venereal Disease Association, the Division of Maternal and Child Health of the Health Resources and Services Administration, the National Institute on Drug Abuse of the Alcohol, Drug Abuse, and Mental Health Administration, the National Hemophilia Foundation, the Haitian Medical Association,

the American Bar Foundation, and the Kennedy Institute of Ethics at Georgetown University. The consultants also included representatives of the departments of health of the areas with the largest number of perinatally transmitted pediatric AIDS cases: New York City, Florida, and New Jersey. These recommendations may not reflect the views of all individual consultants or the organizations they represented.

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APPENDIX III

EDUCATION AND FOSTER CARE OF CHILDREN INFECTED WITH HUMAN T-LYMPHOTROPIC VIRUS TYPE III/LYMPHADENOPATHY-ASSOCIATED VIRUS

(Reprinted from MMWR August 30, 1985)

The information and recommendations contained in this document were developed and compiled by CDC in consultation with individuals appointed by their organizations to represent the Conference of State and Territorial Epidemiologists, the Association of State and Territorial Health Officers, the National Association of County Health Officers, the Division of Maternal Child Health (Health Resources and Services Administration), the National Association for Elementary School Principals, the National Association of State School Nurse Consultants, the National Congress of Parents and Teachers, and the Children's Aid Society. The consultants also included the mother of a child with acquired immune deficiency syndrome (AIDS), a legal advisor to a state education department, and several pediatricians who are experts in the field of pediatric AIDS. This document is made available to assist state and local health and education departments in developing guidelines for their particular situations and locations.

These recommendations apply to all children known to be infected with human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV). This includes children with AIDS as defined for reporting purposes (Table 1); children who are diagnosed by their physicians as having an illness due to infection with HTLV-III/LAV but who do not meet the case definition; and children who are asymptomatic but have virologic or serologic evidence of infection with HTLV-III/LAV. Theses recommendations do not apply to siblings of infected children unless they are also infected.

BACKGROUND

The Scope of the Problem. As of August 20, 1985, 183 of the 12,599 reported cases of AIDS in the United States were among children under 18 years of age. This number is expected to double in the next year. Children with AIDS have been reported from 23 states, the District of Columbia, and Puerto Rico, with 75% residing in New York, California, Florida, and New Jersey.

The 183 AIDS patients reported to CDC represent only the most severe form of HTLV-III/LAV infection, i.e., those children who develop opportunistic infections or malignancies (Table 1). As in adults with HTLV-III/LAV infection many infected children may have milder illness or may be asymptomatic.

Legal Issues. Among the legal issues to be considered in forming guidelines for the education and foster care of HTLV-III/LAV-infected children are the civil rights aspects of public school attendance, the protections for handicapped children under 20 U.S.C. 1401 et seq. and 29 U.S.C. 794, the confidentiality of a student's school record under

state laws and under 20 U.S.C. 1232g, and employee right-to-know statutes for public employees in some states.

TABLE 1.
Provisional case definition for acquired immunodeficiency syndrome (AIDS) surveillance of children

For the limited purposes of epidemiology surveillance, CDC defines a case of pediatric acquired immunodeficiency syndrome (AIDS) as a child who has had:
1. A reliably diagnosed disease at least moderately indicative of underlying cellular immunodeficiency, and
2. No known cause of underlying cellular immunodeficiency or any other reduced resistance reported to be associated with that disease.

The diseases accepted as sufficiently indicative of underlying cellular immunodeficiency are the same as those used in defining AIDS in adults. In the absence of these opportunistic diseases, a histologically confirmed diagnosis of chronic lymphoid interstitial pneumonitis will be considered indicative of AIDS unless test(s) for HTLV-III/LAV are negative. Congenital infections, e.g., toxoplasmosis or herpes simplex virus infection in the first month after birth or cytomegalovirus infection in the first 6 months after birth must be excluded.

Specific conditions that must be excluded in a child are:
1. Primary immunodeficiency diseases--severe combined immunodeficiency, DiGeorge syndrome, Wiskott-Aldrich syndrome, ataxia-teleangiectasis, graft versus host disease, neutropenia fimction abnormality, agammaglobulinemia, or hypogammaglobulinemia with raised IgM.
2. Secondary immunodeficiency associated with immunosuppressive therapy, lymphoreticular malignancy, or starvation.

CONFIDENTIALITY ISSUES. The diagnosis of AIDS or associated illnesses evokes much fear from others in contact with the patient and may evoke suspicion of life styles that may not be acceptable to some persons. Parents of HTLV-III/LAV-infected children should be aware of the potential for social isolation should the child's condition become known to others in the care or educational setting. School, day-care, and social service personnel and others involved in educating and caring for these children should be sensitive to the need for confidentiality and the right to privacy in these cases.

ASSESSMENT OF RISKS

RISK FACTORS FOR ACQUIRING HTLV-III/LAV INFECTION AND TRANSMISSION. In adults and adolescents, HTLV-III/LAV is transmitted primarily through sexual contact (homosexual or heterosexual) and through parental exposure to infected blood or blood products. HTLV-III/LAV has been isolated from blood, semen, saliva, and tears but transmission has not been documented from saliva and tears. Adults at increased risk for acquiring HTLV-III/LAV include homosexual/bisexual men,

intravenous drug abusers, persons transfused with contaminated blood or blood products, and sexual contact of persons with HTLV-III/LAV infection or in groups at increased risk for infection.

The majority of infected children acquire the virus from their infected mothers in the perinatal period (1-4). In utero or intrapartum transmission are likely, and one child reported from Australia apparently acquired the virus postnatally, possibly from ingestion of breast milk (5). Children may also become infected through transfusion of blood or blood products that contain the virus. Seventy percent of the pediatric cases reported to CDC occured among children whose parent had AIDS or was a member of a group at increased risk of acquiring HTLV-III/LAV infection; 20% of the cases occurred among children who had received blood or blood products; and for 10%, investigations are incomplete.

RISK OF TRANSMISSION IN THE SCHOOL, DAY-CARE OR FOSTER-CARE SETTING. None of the identified cases of HTLV-III/LAV infection in the United States are known to have been transmitted in the school, day-care, or foster-care setting or through other casual person-to-person contact. Other than the sexual partners of HTLV-III/LAV-infected patients and infants born to infected mothers, none of the family members of the over 12,000 AIDS patients reported to CDC have been reported to have AIDS. Six studies of family members of patients with HTLV-III/LAV infection have failed to demonstrate HTLV-III/LAV transmission to adults who were not sexual contacts of the infected patients or to older children who were not likely at risk from perinatal transmission (6-11).

Based on current evidence, casual person-to-person contact as would occur among school children appears to pose no risk. However, studies of the risk of transmission through contact between younger children and neurologically handicapped children who lack control of their body secretions are very limited. Based on experience with other communicable diseases, a theoretical potential for transmission would be greatest among these children. It should be emphasized that any theoretical transmission would most likely involve exposure of open skin lesions or mucous membranes to blood and possibly other body fluid of an infected person.

RISKS TO THE CHILD WITH HTLV-III/LAV INFECTION. HTLV-III/LAV infection may result in immunodeficiency. Such children may have a greater risk of encountering infectious agents in a school or day-care setting than at home. Foster homes with multiple children may also increase the risk. In addition, younger children and neurologically handicapped children who may display behaviors such as mouthing of toys, would be expected to be at greater risk for acquiring infections. Immunodepressed children are also at greater risk of suffering severe complications from such infections as chickenpox, cytomegalovirus, tuberculosis, herpes simplex, and measles. Assessment of the risk to the immunodepressed child is best made by the child's physician who is aware of the child's immune status. The risk of acquiring some infections, such as chickenpox, may be reduced by prompt use of specific immune globulin following a known exposure.

RECOMMENDATIONS

1. Decisions regarding the type of educational and care setting for HTLV-III/LAV-infected children should be based on the behavior, neurologic development, and physical condition of the child and the expected type of interaction with others in that setting. These decisions are best made using the team approach including the child's physician, public health personnel, the child's parent or guardian, and personnel associated with the proposed care or educational setting. In each case, risks and benefits to both the infected child and to others in the setting should be weighed.
2. For most infected school-aged children, the benefits of an unrestricted setting would outweigh the risks of their acquiring potentially harmful infections in the setting and the apparent nonexistent risk of transmission of HTLV-III/LAV. These children should be allowed to attend school and after-school day-care and to be placed in a foster home in an unrestricted setting.
3. For the infected preschool-aged child and for some neurologically handicapped children who lack control of their body secretions or who display behavior, such as biting, and those children who have uncoverable oozing lesions, a more restricted environment is advisable until more is known about transmission in these settings. Children infected with HTLV-III/LAV should be cared for and educated in settings that minimize exposure of other children to blood or body fluids.
4. Care involving exposure to the infected child's body fluid and excrement, such as feeding and diaper changing, should be performed by persons who are aware of the child's HTLV-III/LAV-infected person, good handwashing after exposure to blood and body fluids and before caring for another child should be observed, and gloves should be worn if open lesions are present on the caretaker's hands. Any open lesions on the infected person should also be covered.
5. Because other infections in addition to HTLV-III/LAV can be present in fluids, all schools and day-care facilities, regardless of whether children with HTLV-III/LAV infection are attending, should adopt routine procedures for handling blood or body fluids. Soiled surfaces should be promptly cleaned with disinfectants, such as household bleach (diluted 1 part bleach to 10 parts water). Disposable towels or tissues should be used whenever possible, and mops should be rinsed in the disinfectant. Those who are cleaning should avoid exposure of open skin lesions or mucous membranes to the blood or body fluids.
6. The hygienic practices of children with HTLV-III/LAV infection may improve as the child matures. Alternatively, the hygienic practices may deteriorate if the child's condition worsens. Evaluation to assess the need for a restricted environment should be performed regularly.
7. Physicians caring for children born to mothers with AIDS or at increased risk of acquiring HTLV-III/LAV infection should consider testing the children for evidence of HTLV-III/LAV infection for medical reasons. For example, vaccination of infected children with live virus vaccines, such as measles-

mumps-rubella vaccine (MMWR), may be hazardous. These children also need to be followed closely for problems with growth and development and given prompt and aggressive therapy for infections and exposure to potentially lethal infections, such as varicella. In the event that an antiviral agent or other therapy for HTLV-III/LAV infection becomes available, these children should be considered for such therapy. Knowledge that a child is infected will allow parents and other care-takers to take precautions when exposed to the blood and body fluids of the child.

8. Adoption and foster-care agencies should consider adding HTLV-III/LAV screening to their routine medical evaluations of children at increased risk of infection before placement in the foster or adoptive home, since these parents must make decisions regarding the medical care of the child and must consider the possible social and psychological effects on their families.
9. Mandatory screening as a condition for school entry is not warranted based on available data.
10. Persons involved in the care and education of HTLV-III/LAV-infected children should respect the child's right to privacy, including maintaining confidential records. The number of personnel who are aware of the child's condition should be kept at a minimum needed to assure proper care of the child and to detect situations where the potential for transmission may increase (e.g., bleeding injury).
11. All educational and public departments, regardless of whether HTLV-III/LAV-infected children are involved, are strongly encouraged to inform parents, children, and educators regarding HTLV-III/LAV and its transmission. Such education would greatly assist efforts to provide the best care and education for infected children while minimizing the risk of transmission to others.

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Recommendations for Preventing Possible Transmission of Human T-Lymphotropic virus Type III/ Lymphadenopathy-Associated Virus from Tears

Human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV), the etiologic agent of acquired immunodeficiency syndrome (AIDS), has been found in various body fluids, including blood, semen, and saliva. Recently, scientists at the National Institutes of Health isolated the virus from the tears of an AIDS patient (1). The patient, a 33 year old woman with a history of Pneumocystis carinii pneumonia and disseminated Mycobacterium avium-intracellulare infection, had no ocular complaints, and her eye examination was normal. Of the tear samples obtained from six other patients with AIDS or related conditions, three showed equivocal culture results, and three were culture negative.

The following precautions are judged suitable to prevent spread of HTLV-III/LAV and other microbial pathogens that might be present in tears. They do not apply to the procedures used by individuals in caring for their own lenses, since the concern is the possible virus transmission between individuals.

1. Health care professionals performing eye examinations or other procedures involving contact with tears should wash their hands immediately after a procedure and between patients. Handwashing alone should be sufficient, but when practical and convenient, disposable gloves may be worn. The use of gloves is advisable when there are cuts, scratches, or dermatologic lesions on the hands. Use of other measures, such as masks, goggles, or gowns, is not indicated.
2. Instruments that come into direct contact with external surfaces of the eye should be wiped clean and then disinfected by: (1) a 5- to 10-minute exposure to a fresh solution of 3% hydrogen peroxide; or (b) a fresh solution containing 5,000 parts per million (mg/L) free available chlorine--a 1/10 dilution of common household bleach (sodium hypo-chloride); or (c) 70% ethanol; or (d) 70% isopropanol. The device should be thoroughly rinsed with tap water and dried before reuse.

3. Contact lenses used in trial fittings should be disinfected between fittings by one of the following regimens: a) Disinfection of trial hard lenses with a commercially available hydrogen peroxide contact lens disinfecting system currently approved for soft contact lenses. (Other hydrogen peroxide disinfecting preparations may contain preservatives that could discolor the lenses). Alternatively, most trial hard lenses can be treated with the standard heat disinfection regimen used for soft lenses (78-80 c [172-176 f] for 10 minutes). Practitioners should check with hard lens suppliers to ascertain which lenses can be safely heat-treated. b. Rigid Gas permeable (RGP) trial fitting lenses can be disinfected using the above hydrogen peroxide disinfection system. RGP lenses may warp if they are heat-disinfected. c. Soft trial fitting lenses can be disinfected using the same hydrogen peroxide system.. Some soft lenses have also been approved for heat disinfection. Other than hydrogen peroxide, the chemical disinfectants used in standard contact lens solutions have not yet been tested for their activity against HTLV-III/LAV. Until other disinfectants are shown to be suitable for disinfecting HTLV-III/LAV, contact lenses used in the eyes of patients suspected or known to be infected with HTLV-III/LAV are most safely handled by hydrogen peroxide disinfection.

The above recommendations are based on data from supplies conducted at the National Institutes of Health and CDC on disinfection/inactivation of HTLV-III/LAV virus (2-4). Additional information regarding general hospital and laboratory precautions have been previously published (5-9).

EDITORIAL NOTE: All secretions and excretions of an infected person may contain lymphocytes, host cells for HTLV-III/LAV; therefore, thorough study of these fluids might be expected to sometimes yield this virus. Despite positive cultures from a variety of body fluids of infected persons, however, spread from infected persons to household contacts who have no other identifiable risks for infection has not been documented. Furthermore, there is no evidence to date that HTLV-III/LAV has been transmitted through contact with the tears of infected individuals or through medical instruments used to examine AIDS patients.

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APPENDIX IV

TESTING DONORS OF ORGANS, TISSUES, AND SEMEN FOR ANTIBODY TO HUMAN T-LYMPHOTROPHIC VIRUS TYPE III/LYMPHADENOPATHY-ASSOCIATED VIRUS

(Reprinted from MMWR, May 24, 1985)

The U.S. Public Health Service has recommended that all donated blood and plasma be tested for antibody to human T-lymphotrophic virus type III/lymphadenopathy-associated virus (HTLV-III), the virus that causes acquired immuno-deficiency syndrome (AIDS) (1) It is additionally recommended that blood or serum from donors of organs, tissues, or semen intended for human use be similarly tested and that the result be used to evaluate the appropriate use of such materials from these donors. Although AIDS has not been reported to have been associated with such use, semen and other body fluids, including blood, may harbor the virus. Thus, organs, tissues, and semen obtained from HTLV-III/LAV antibody-positive persons must be considered as potentially infectious. Persons in groups having an increased risk for AIDS should not donate organs, tissues, or semen regardless of the result of the antibody test, this is the same policy currently followed for blood donations. It is recognized that the circumstances of organ procurement and the logistics of transplantation may in some instances not permit the use of an HTLV-III/LAV test. However, when feasible such testing is prudent.

Reported by U.S. Food and Drug Administration; Alcohol Drug Abuse, and Mental Health Administration; National Institutes of Health; Health Resources and Svcs Administration; CDC.

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1. CDC. Provisional Public Health Service inter-agency recommendations for screening donated blood and plasma for antibody to the virus causing acquired immunodeficiency syndrome. MMWR 1985;34:1-5.

APPENDIX V

Revised Public Health Service Definition of Persons Who Should Refrain from Donating Blood and Plasma-United States: (Reprinted from MMWR, September 6, 1985)

Since March 1985, blood- and plasma-collection centers in the United States have used a two-phase screening procedure to decrease transmission of human T-lymphotropic virus type III (HTLV-III) through transfusion of blood or blood products. First, potential donors are informed that if they have a risk factor for AIDS they should not donate (1); second, the blood or plasma of persons accepted as donors is screened for antibody to HTLV-III (2,3). The low frequency of enzyme immunoassay (EIA)-positive tests among blood donors (3,4) shows that the deferral criteria have been effective. Interviews with the small number of blood donors found infected with HTLV-III, however, have shown that most have a risk factor for HTLV-III infection; homosexual contact was the most common risk factor identified (5). To further reduce the risk of HTLV-III infection from blood plasma, the U.S. Food and Drug Administration (FDA) has reworded the donor-referral recommendations to state that any man who has had sex with another man since 1977 should not donate blood or plasma. This applies even to men who may have had only a single contact and who do not consider themselves homosexual or bisexual.

Reported by Center for Drugs and Biologics, US Food and Drug Administration; AIDS Br, Div of Viral Diseases, Centers for Infectious Diseases, CDC.

EDITORIAL NOTE: Recommendations to decrease transmission of HTLV-III through transfusion of blood or blood products were disseminated in March 1983 (1) and were rapidly adopted by blood and plasma centers throughout the United States. These recommendations centered on informing all blood or plasma donors that people with a risk factor for AIDS should not donate and asked for voluntary compliance. In March 1985, the second phase of screening blood and plasma was instituted with licensure of test kits to detect antibody to HTLV-III (2,3). The test kits are both highly sensitive and specific (4), but donors with a risk factor for HTLV-III infection continue to be asked not to donate blood, since the two-phase screening procedure provides additional safety. This revised wording of the deferral recommendations is intended to inform persons who may have been infected with HTLV-III through occasional or intermittent homosexual activity that they should not donate blood or plasma, even if they do not believe they are at risk of having been infected through their contact.

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APPENDIX VI

REVISION OF THE CASE DEFINITION OF ACQUIRED IMMUNODEFICIENCY SYNDROME FOR NATIONAL REPORTING--UNITED STATES
(Reprinted from MMWR June 28, 1985)

Patients with illnesses that, in retrospect, were manifestations of acquired immunodeficiency syndrome (AIDS) were first described in the summer of 1981 (1.2). A case definition of AIDS for national reporting was first published in the MMWR in September 1982 (3.4). Since then, the defintion has undergone minor revisions in the list of diseases used as indications of underlying cellular deficiency (5.8).

Since the 1982 definition was published, human T-lymphotrophic virus type III lymphadenopathy-associated virus (HTLV-III/LAV) has been recognized as the cause of AIDS. The clinical manifestations of HTLV-III/LAV infection may be directly attributable to infection with this virus or the result of secondary conditions occuring as a consequence of immune dysfunction caused by the underlying infection with HTLV-III/LAV. The range of manifestations may include none, nonspecific signs and symptoms of illness, autoimmune and neurologic disorders, a variety of opportunistic infections, and several types of malignancy. AIDS was defined for national reporting before its etiology was known and has encompassed only certain secondary conditions that reliably reflected the presence of a severe immune dysfunction. Current laboratory test to detect HTLV-III/LAV antibody make it possible to include additional serious conditions in the syndrome, as well as to further improve the specificity of the definition used for reporting cases.

The current case definition of AIDS has provided useful data on disease trends, because it is precise, consistently interpreted, and highly specific. Other manifestations of HTLV-III/LAV infections and asymptomatic infections may be reportable in some states and cities but will not be nationally reportable. Because persons with less specific or milder manifestations of HTLV-III/LAV infection may be important in transmitting the virus, estimates of the number of such persons are of value. These estimates can be obtained through epidemiologic studies or special surveys in specific poplulations.

Issues related to the case defintion of AIDS were discussed by the Conference of State and Territorial Epidemiologists (CSTE) and its annual meeting in Madison, Wisconsin, June 2-5, 1985.

The CSTE approved the following resolutions:

1. that the case definition of AIDS used for national reporting continue include only the more severe manifestations of HTLV-III/LAV infection; and
2. that CDC develop more inclusive definitions and classifications of HTLV-III/LAV infection for diagnosis, treatment, and prevention, as well as for epidemiologic studies and special surveys; and
3. that the following refinements be adopted in the case definition of AIDS used for national reporting:

a. In the absence of the opportunistic disease required by the current case definition, any of the following disease will be considered indicative of AIDS if the patient has a positive serologic or virologic test for HTLV-III/LAV:
   (1) disseminated histoplasmosis (not confined to lungs or lymph nodes), diagnosed by culture, histology, or antigen detection;
   (2) isosporiasis, causing chronic diarrhea (over 1 month), diagnosed by histology or stool microscopy;
   (3) bronchial or pulmonary candidiasis, diagnosed by microscopy or by presence of characteristic white plaques grossly on the bronchial mucosa (not by culture alone);
   (4) non-Hodgkin's lymphoma of high-grade pathologic type (diffuse, undifferentiated) and of B-cell or unknown immunologic pheno-type, diagnosed by biopsy;
   (5) histologically confirmed Kaposi's sarcoma in patients who are 60 years old or older when diagnosed.
b. In the absence of the opportunistic disease required by the current case defintion, a histologically confirmed diagnosis of chronic lymphoid interstitial pneumonitis in a child (under 13 years of age) will be considered indicative of AIDS unless test(s) for HTLV-III/LAV are negative.
c. Patients who have a lymphoreticular malignancy diagnosed more than 3 months after the diagnosis of an opportunistic disease used as a marker for AIDS will no longer be excluded as AIDS cases.
d. To increase the specificity of the case definition, patients will be excluded as AIDS cases if they have a negative result on testing for serum antibody to HTLV-III/LAV, have no other type of HTLV-III/LAV test with a positive result, and do not have a low number of T-helper lymphocytes or a low ratio of T-helper to T-suppressor lymphocytes. In the absence of test results, patients satisfying all other criteria in the definition will continue to be included.

CDC will immediately adopt the above amendments to the case definition of AIDS for national reporting. This revision in the case definition will result in the reclassification of less than 1% of cases previously reported to CDC. The number of additional new cases reportable as a result of the revision is expected to be small. Cases included under the revised defintion will be distinguishable from cases included under the old defintion so as to provide a consistent basis for interpretation of trends. CDC will also develop draft classifications for disease manifestations of HTLV-III/LAV infections other than AIDS, distribute these widely for comment, and publish the results.

Reported by Conference of State and Territorial Epidemiologists; AIDS Br, Div of Viral Diseases, Center for Infectious Diseases, CDC.

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APPENDIX VII

RECOMMENDATIONS FOR PREVENTING TRANSMISSION OF INFECTION WITH HUMAN T-LYMPHOTROPIC VIRUS TYPE III/LYMPHADENOPATHY-ASSOCIATED VIRUS DURING INVASIVE PROCEDURES

(Reprinted from MMWR, April 11, 1986)

BACKGROUND

On November 15, 1985, "Recommendations for Preventing Transmission of Infection with Human T-Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus in the Workplace," was published (1). That document gave particular emphasis to health-care settings and indicated that formulation of further specific recommendations for preventing human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV) transmission applicable to health-care workers (HCWs) who perform invasive procedures was in progress. Toward that end, a 2-day meeting was held at CDC to discuss draft recommendations applicable to individuals who perform or assist in invasive procedures.*

Following the meeting, revised draft recommendations for HCWs who have contact with tissues or mucous membranes while performing or assisting in operative, obstetric, or dental invasive procedures were sent to participants for comment. In addition, 10 physicians with expertise in infectious diseases and the epidemiology of HTLV-III/LAV infection were consulted to determine whether they felt additional measures or precautions beyond those recommended below were indicated. These 10 experts did not feel that additional recommendations or precautions were indicated.

DEFINITIONS

In this document, an operative procedure is defined as surgical entry into tissues, cavities, or organs or repair of major traumatic injuries in an operating or delivery room, emergency department, or outpatient setting, including both physicians "and dentists" offices. An obstetric procedure is defined as a vaginal or cesarean delivery or other invasive obstetric procedure where bleeding may occur. A dental procedure is defined as the manipulation, cutting, or removal of any oral or perioral tissues, including tooth structure, where bleeding occurs or the potential for bleeding exists.

RECOMMENDATIONS

There have been no reports of HTLV-III/LAV transmission from an HCW to a patient or from a patient to an HCW during operative, obstetric, or dental invasive procedures. Nevertheless, special emphasis should be placed on the following precautions to prevent transmission of bloodborne agents between all patients and all HCWs who perform or assist in invasive procedures.

1. All HCWs who perform or assist in operative, obstetric, or dental invasive procedures must be educated regarding the epidemiology, modes of transmission, and prevention of HTLV-III/LAV infection and the need for routine use of appropriate barrier precautions

during procedures and when handling instruments contaminated with blood after procedures.

2. All HCWs who perform or assist in invasive procedures must wear gloves when touching mucous membranes or nonintact skin of all patients and use other appropriate barrier precautions when indicated (e.g., masks, eye coverings, and gowns, if aerosolization or splashes are likely to occur). In the dental setting, as in the operative and obstetric setting, gloves must be worn for touching all mucous membranes and changed between all patient contacts. If a glove is torn or a needlestick or other injury occurs, the glove must be changed as promptly as safety permits and the needle or instrument removed from the sterile field.

3. All HCWs who perform or assist in vaginal or cesarean deliveries must use appropriate barrier precautions (e.g., gloves and gowns) when handling the placenta or the infant until blood and amniotic fluid have been removed from the infant's skin. Recommendations for assisting in the prevention of perinatal transmission of HTLV-III/LAV have been published (2).

4. All HCWs who perform or assist in invasive procedures must use extraordinary care to prevent injuries to hands caused by needles, scalpels, and other sharp instruments or devices during procedures; when cleaning used instruments; during disposal of used needles; and when handling sharp instruments following procedures. After use, disposable syringes and needles, scalpel blades, and other sharp items must be placed in puncture-resistant containers for disposal. To prevent needlestick injuries, needles should not be recapped; purposefully bent or broken; removed from disposable syringes; or otherwise manipulated by hand. No data are currently available from controlled studies examining the effect, if any, of the use of needle-cutting devices on the incidence of needlestick injuries.

5. If an incident occurs during an invasive procedure that results in exposure of a patient to the blood of an HCW, the patient should be informed of the incident, and previous recommendations for management of such exposures (1) should be followed.

6. No HCW who has exudative lesions or weeping dermatitis should perform or assist in invasive procedures or other direct patient-care activities or handle equipment used for patient care.

7. All HCWs with evidence of any illness that may compromise their ability to adequately and safely perform invasive procedures should be evaluated medically to determine whether they are physically and mentally competent to perform invasive procedures.

8. Routine serologic testing for evidence of HTLV-III/LAV infection is not necessary for HCWs who perform or assist in invasive procedures or for patients undergoing invasive procedures, since the risk of transmission in this setting is so low. Results of such routine testing would not practically supplement the precautions recommended above in further reducing the negligible risk of

transmission during operative, obstetric, or dental invasive procedures.

Previous recommendations (1,3,4) should be consulted for: (1) preventing transmission of HTLV-III/LAV infection from HCWs to patients and patients to HCWs in health-care settings other than those described in this document; (2) preventing transmission from patient to patient; (3) sterilizing, disinfecting, housekeeping, and disposing of waste; and (4) managing parenteral and mucous-membrane exposures of HCWs and patients. Previously recommended precautions (1) are also applicable to HCWs performing or assisting in invasive procedures.

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*The following organizations were represented at the meeting: American Academy of Family Physicians; American Academy of Periodontology; American Association of Dental Schools; American Association of Medical Colleges; American Association of Oral and Maxillofacial Surgeons; American Association of Physicians for Human Rights; American College of Emergency Physicians; American College of Nurse Midwives; American College of Obstetricians and Gynecologists; American College of Surgeons; American Dental Association; American Dental Hygienists Association; American Hospital Association; American Medical Association; American Nurses' Association; American Public Health Association; Association for Practitioners in Infection Control; Association of Operating Room Nurses; Association of State and Territorial Health Officials; Conference of State and Territorial Epidemiologists; U.S. Food and Drug Administration; Infectious Diseases Society of America; National Association of County Health Officials; National Dental Association; National Institutes of Health; National Medical Association; Nurses Association of the American College of Obstetricians and Gynecologists; Society of Hospital Epidemiologists of America; Surgical Infection Society; and United States Conference of Local Health Officers. In addition, a hospital administrator, a hospital medical director, and representatives from CDC participated in the meeting. These recommendations may not reflect the views of all individual consultants or the organizations they represented.

APPENDIX VIII

RECOMMENDED INFECTION-CONTROL PRACTICES FOR DENTISTRY
(Reprinted from MMWR, April 18, 1986)

Dental personnel may be exposed to a wide variety of microorganisms in the blood and saliva of patients they treat in the dental operatory. These include Mycobacterium tuberculosis, hepatitis B virus, staphylococci, streptococci, cytomegalovirus, herpes simplex virus types I and II, human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV), and a number of viruses that infect the upper respiratory tract. Infections may be transmitted in dental practice by blood or saliva through direct contact, droplets, or aerosols. Although not documented, indirect contact transmission of infection by contaminated instruments is possible. Patients and dental health-care workers (DHCWs) have the potential of transmitting infections to each other (1).

A common set of infection-control strategies should be effective for preventing hepatitis B, acquired immunodeficiency syndrome, and other infectious diseases caused by bloodborne viruses (2-4). The ability of hepatitis B virus to survive in the environment (5) and the high titers of virus in blood (6) make this virus a good model for infection-control practices to prevent transmission of a large number of other infectious agents by blood or saliva. Because all infected patients cannot be identified by history, physical examination, or readily available laboratory tests (3), the following recommendations should be used routinely in the care of all patients in dental practices.

MEDICAL HISTORY

Always obtain a thorough medical history. Include specific questions about medications, current illnesses, hepatitis, recurrent illnesses, unintentional weight loss, lymphadenopathy, oral soft tissue lesions, or other infections. Medical consultation may be indicated when a history of active infection or systemic disease is elicited.

USE OF PROTECTIVE ATTIRE AND BARRIER TECHNIQUES

1. For protection of personnel and patients, gloves must always be worn when touching blood, saliva, or mucous membranes (7-10). Gloves must be worn by DHCWs when touching blood-soiled items, body fluids, or secretions, as well as surfaces contaminated with them. Gloves must be worn when examining all oral lesions. All work must be completed on one patient, where possible, and the hands must be washed and regloved before performing procedures on another patient. Repeated use of a single pair of gloves is not recommended, since such use is likely to produce defects in the glove material, which will diminish its value as an effective barrier.

2. Surgical masks and protective eyewear or chin-length plastic face shields must be worn when splashing or spattering of blood or other body fluids is likely, as is common in dentistry (11,12).

3. Reusable or disposable gowns, laboratory coats, or uniforms must be worn when clothing is likely to be soiled with blood or other body fluids. If reusable gowns are worn, they may be washed, using a normal laundry cycle. Gowns should be changed at least daily or when visibly soiled with blood (13).

4. Impervious-backed paper, aluminum foil, or clear plastic wrap may be used to cover surfaces (e.g., light handles or x-ray unit heads) that may be contaminated by blood or saliva and that are difficult or impossible to disinfect. The coverings should be removed (while DHCWs are gloved), discarded, and then replaced (after ungloving) with clean material between patients.

5. All procedures and manipulations of potentially infective materials should be performed carefully to minimize the formation of droplets, spatters, and aerosols, where possible. Use of rubber dams, where appropriate, high-speed evacuation, and proper patient positioning should facilitate this process.

HANDWASHING AND CARE OF HANDS

Hands must always be washed between patient treatment contacts (following removal of gloves), after touching inanimate objects likely to be contaminated by blood or saliva from other patients, and before leaving the operatory. The rationale for handwashing after gloves have been worn is that gloves become perforated, knowingly or unknowingly, during use and allow bacteria to enter beneath the glove material and multiply rapidly. For many routine dental procedures, such as examinations and nonsurgical techniques, handwashing with plain soap appears to be adequate, since soap and water will remove transient microorganisms acquired directly or indirectly from patient contact (13). For surgical procedures, an antimicrobial surgical handscrub should be used (14). Extraordinary care must be used to avoid hand injuries during procedures. However, when gloves are torn, cut, or punctured, they must be removed immediately, hands thoroughly washed, and regloving accomplished before completion of the dental procedure. DHCWs who have exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling dental patient-care equipment until the condition resolves (15).

USE AND CARE OF SHARP INSTRUMENTS AND NEEDLES

1. Sharp items (needles, scalpel blades, and other sharp instruments) should be considered as potentially infective and must be handled with extraordinary care to prevent unintentional injuries.

2. Disposable syringes and needles, scalpel blades, and other sharp items must be placed into puncture-resistant containers located as close as practical to the area in which they were used. To prevent needlestick injuries, disposable needles should not be recapped; purposefully bent or broken; removed from disposable syringes; or otherwise manipulated by hand after use.

3. Recapping of a needle increases the risk of unintentional needlestick injury. There is no evidence to suggest that reusable aspirating-type syringes used in dentistry should be handled differ-

ently from other syringes. Needles of these devices should not be recapped, bent, or broken before disposal.

4. Because certain dental procedures on an individual patient may require multiple injections of anesthetic or other medications from a single syringe, it would be more prudent to place the unsheathed needle into a 'sterile field' between injections rather than to recap the needle between injections. A new (sterile) syringe and a fresh solution should be used for each patient.

INDICATIONS FOR HIGH-LEVEL DISINFECTION OR STERILIZATION OF INSTRUMENTS

Surgical and other instruments that normally penetrate soft tissue and/or bone (e.g., forceps, scalpels, bone chisels, scalers, and surgical burs) should be sterilized after each use. Instruments that are not intended to penetrate oral soft tissues or bone (e.g., amalgam condensers, plastic instruments, and burs) but that may come into contact with oral tissues should also be sterilized after each use, if possible; however, if sterilization is not feasible, the latter instruments should receive high-level disinfection (3,13,16).

METHODS FOR HIGH-LEVEL DISINFECTION OR STERILIZATION

Before high-level disinfection or sterilization, instruments should be cleaned to remove debris. Cleaning may be accomplished by a thorough scrubbing with soap and water or a detergent, or by using a mechanical device (e.g., an ultrasonic cleaner). Persons involved in cleaning and decontaminating instruments should wear heavy-duty rubber gloves to prevent hand injuries. Metal and heat-stable dental instruments should be routinely sterilized between use by steam under pressure (autoclaving), dry heat, or chemical vapor.

The adequacy of sterilization cycles should be verified by the periodic use of spore-testing devices (e.g., weekly for most dental practices) (13). Heat- and steam-sensitive chemical indicators may be used on the outside of each pack to assure it has been exposed to a sterilizing cycle. Heat-sensitive instruments may require up to 10 hours' exposure in a liquid chemical agent registered by the U.S. Environmental Protection Agency (EPA) as a disinfectant/sterilant; this should be followed by rinsing with sterile water. High-level disinfection may be accomplished by immersion in either boiling water for at least 10 minutes or an EPA-registered disinfectant/sterilant chemical for the exposure time recommended by the chemical's manufacturer.

DECONTAMINATION OF ENVIRONMENTAL SURFACES

At the completion of work activities, countertops and surfaces that may have become contaminated with blood or saliva should be wiped with absorbent toweling to remove extraneous organic material, then disinfected with a suitable chemical germicide. A solution of sodium hypochlorite (household bleach) prepared fresh daily is an inexpensive and very effective germicide. Concentrations ranging from 5,000 ppm (a 1:10 dilution of household bleach) to 500 ppm (a 1:100 dilution) sodium hypochlorite are effective, depending on the amount of organic material (e.g., blood, mucus, etc.) present on the surface to be cleaned and disinfected. Caution should be exercised, since sodium hypochlorite is corrosive to metals, especially aluminum.

DECONTAMINATION OF LABORATORY SUPPLIES AND MATERIALS

Blood and saliva should be thoroughly and carefully cleaned from laboratory supplies and materials that have been used in the mouth (e.g., impression materials, bite registration), especially before polishing and grinding intra-oral devices. Materials, impressions, and intra-oral appliances should be cleaned and disinfected before being handled, adjusted, or sent to a dental laboratory (17). These items should also be cleaned and disinfected when returned from the dental laboratory and before placement in the patient's mouth. Because of the ever-increasing variety of dental materials used intra-orally, DHCWs are advised to consult with manufacturers as to the stability of specific materials relative to disinfection procedures.

A chemical germicide that is registered with the EPA as a "hospital disinfectant" and that has a label claim for mycobactericidal (e.g., tuberculocidal) activity is preferred, because mycobacteria represent one of the most resistant groups of microorganisms; therefore, germicides that are effective against mycobacteria are also effective against other bacterial and viral pathogens (15). Communication between a dental office and a dental laboratory with regard to handling and decontamination of supplies and materials is of the utmost importance.

USE AND CARE OF ULTRASONIC SCALERS, HANDPIECES, AND DENTAL UNITS

1. Routine sterilization of handpieces between patients is desirable; however, not all handpieces can be sterilized. The present physical configurations of most handpieces do not readily lend them to high-level disinfection of both external and internal surfaces (see 2 below); therefore, when using handpieces that cannot be sterilized, the following cleaning and disinfection procedures should be completed between each patient: After use, the handpiece should be flushed (see 2 below), then thoroughly scrubbed with a detergent and water to remove adherent material. It should then be thoroughly wiped with absorbent material saturated with a chemical germicide that is registered with the EPA as a "hospital disinfectant" and is mycobactericidal at use-dilution (15). The disinfecting solution should remain in contact with the handpiece for a time specified by the disinfectant's manufacturer. Ultrasonic scalers and air/water syringes should be treated in a similar manner between patients. Following disinfection, any chemical residue should be removed by rinsing with sterile water.

2. Because water retraction valves within the dental units may aspirate infective materials back into the handpiece and water line, check valves should be installed to reduce the risk of transfer of infective material (18). While the magnitude of this risk is not known, it is prudent for water-cooled handpieces to be run and to discharge water into a sink or container for 20-30 seconds after completing care on each patient. This is intended to physically flush out patient material that may have been aspirated into the handpiece or water line. Additionally, there is some evidence that overnight bacterial accumulation can be significantly reduced by allowing water-cooled handpieces to run and to discharge water

into a sink or container for several minutes at the beginning of the clinic day (19). Sterile saline or sterile water should be used as a coolant/irrigator when performing surgical procedures involving the cutting of soft tissue or bone.

HANDLING OF BIOPSY SPECIMENS

In general, each specimen should be put in a sturdy container with a secure lid to prevent leaking during transport. Care should be taken when collecting specimens to avoid contamination of the outside of the container. If the outside of the container is visibly contaminated, it should be cleaned and disinfected, or placed in an impervious bag (20).

DISPOSAL OF WASTE MATERIALS

All sharp items (especially needles), tissues, or blood should be considered potentially infective and should be handled and disposed of with special precautions. Disposable needles, scalpels, or other sharp items should be placed intact into puncture-resistant containers before disposal. Blood, suctioned fluids, or other liquid waste may be carefully poured into a drain connected to a sanitary sewer system. Other solid waste contaminated with blood or other body fluids should be placed in sealed, sturdy impervious bags to prevent leakage of the contained items. Such contained solid wastes can then be disposed of according to requirements established by local or state environmental regulatory agencies and published recommendations (13,20).

Developed by Dental Disease Prevention Activity, Center for Prevention Svcs, Hospital Infections Program, Center for Infectious Diseases, CDC.

Editorial Note: All DHCWs must be made aware of sources and methods of transmission of infectious diseases. The above recommendations for infection control in dental practices incorporate procedures that should be effective in preventing the transmission of infectious agents from dental patients to DHCWs and vice versa. Assessment of quantifiable risks to dental personnel and patients for specific diseases requires further research. There is no current documentation of patient-to-patient blood- or saliva-borne disease transmission from procedures performed in dental practice. While few in number, reported outbreaks of dentist-to-patient transmission of hepatitis B have resulted in serious and even fatal consequences (9).

Herpes simplex virus has been transmitted to over 20 patients from the fingers of a DHCW (10). Serologic markers for hepatitis B in dentists have increased dramatically in the United States over the past several years, which suggests current infection-control practices have been insufficient to prevent the transmission of this infectious agent in the dental operatory. While vaccination for hepatitis B is strongly recommended for dental personnel (21), vaccination alone is not cause for relaxation of strict adherence to accepted methods of asepsis, disinfection, and sterilization.

Various infection-control guidelines exist for hospitals and other clinical settings. Dental facilities located in hospitals and other institutional settings have generally utilized existing guidelines for

institutional practice. These recommendations are offered as guidance to DHCWs in noninstitutional settings for enhancing infection-control practices in dentistry; they may be useful in institutional settings also.

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APPENDIX IX

SAFETY OF THERAPEUTIC IMMUNE GLOBULIN PREPARATIONS WITH RESPECT TO TRANSMISSION OF HUMAN T-LYMPHOTROPIC VIRUS TYPE III/ LYMPHADENOPATHY-ASSOCIATED VIRUS INFECTION

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Immune globulins produced by plasma fractionation methods approved for use in the United States have not been implicated in the transmission of infectious agents. Nevertheless, because immune globulins manufactured before 1985 were derived from plasma of human donors who were not screened for antibody to human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV), CDC and the U.S. Food and Drug Administration (FDA) have received inquiries concerning the safety of immune globulin (IG), hepatitis B immune globulin (HBIG), and intravenous immune globulin (IVIG). Current epidemiologic and laboratory evidence shows that these preparations carry no discernable risk of transmitting HTLV-III/LAV infection and that current indications for their clinical use should not be changed based on such concerns.

BACKGROUND

The IG, HBIG, IVIG, and other special immune globulins used in the United States are produced by several manufacturers using the Cohn-Oncley fractionation process (1,2). This process involves a series of precipitation steps performed in the cold with addition of varying concentrations of ethanol. Production lots of IG and IVIG are made from plasma pools from at least 1,000 donors; HBIG and other specific immune globulins (e.g., varicella-zoster IG) may be prepared from plasma pools from fewer donors.

Before 1985, donors were screened only for hepatitis B surface antigen but not by other tests for specific diagnosis of viral infections. Since April 1985, all donor units also have been screened for antibodies to HTLV-III/LAV, and all repeatedly reactive units have been discarded. Tests conducted at FDA and CDC have shown that as many as two-thirds of HBIG lots, as well as some lots of IG and IVIG, produced between 1982 and 1985 may have been positive for HTLV-III/LAV antibody. The question of safety arises out of concern that some immune globulins currently available were prepared from plasma pools that included units from donors who may have had HTLV-III/LAV viremia.

EPIDEMIOLOGIC STUDIES

Several studies have shown that recipients of HBIG and IG, including recipients of lots known to be positive for antibody to HTLV-III/LAV, did not seroconvert to antibody to HTLV-III/LAV-positivity and have not developed signs and symptoms of acquired immunodeficiency syndrome (AIDS) or other illnesses suggesting HTLV-III/LAV infection.

Since August 1983, CDC has enrolled 938 individuals who have had parenteral or mucous-membrane exposures to blood or body fluids of AIDS patients in a prospective surveillance study. To date, 451

entrants have been followed and tested for HTLV-III/LAV antibody. Of these, 183 persons received IG and/or HBIG as prophylaxis against hepatitis B infection; 100 (55%) received only IG; 65 (36%) received only HBIG; and 18 (10%) received both. One of the 183 HBIG recipients is now positive for HTLV-III/LAV antibody, but no preexposure serum was available for this individual, and seropositivity may have predated the needlestick exposure and IG prophylaxis. Further, heterosexual transmission of HTLV-III/LAV infection in this individual cannot be ruled out. No documented seroconversions have occurred in any of the 183 health-care workers who received IG or HBIG. Studies have been reported of 16 subjects who received HBIG that was strongly positive for HTLV-III/LAV antibody (3). Each patient had been given one to five ampules. A total of 31 doses were administered to 16 individuals. Low levels of passively acquired HTLV-III/LAV antibody were detected shortly after injection, but reactivity did not persist. Six months after the last HBIG injection, none of the 16 individuals had antibody to HTLV-III/LAV.

In a study of prophylaxis against cytomegalovirus (CMV) infections among kidney-transplant patients, 16 patients received CMV-specific IVIG preparations subsequently found to contain HTLV-III/LAV antibody. After 10 months or longer of follow-up, none of the 16 recipients developed antibody or other evidence of HTLV-III/LAV infection.

In studies of a group of IVIG recipients, most of whom had idiopathic thrombocytopenia, none of 134 patients developed antibodies or other evidence of HTLV-III/LAV infection. Information regarding past therapy with immune globulins is available from 10,227 of 17,115 AIDS patients reported to CDC. Three hundred fifty-eight (4%) reported receipt of an IG preparation. All but seven of these patients also were members of groups known to be at high risk for developing AIDS. The percentage of patients with no recognized risk factors for AIDS was not significantly different among those who received immune globulins (7/358 (2%)) than among those who did not (358/9,869 (4%)).

LABORATORY STUDIES

Scientists at FDA recently evaluated the basic fractionation processes (1,2) used for production of immune globulins to determine effectiveness of those procedures in eliminating HTLV-III/LAV infectivity (4). Six sequential steps in a typical process were evaluated. The study was designed so that efficiency of eliminating HTLV-III/LAV at each step was measured. The degree to which HTLV-III/LAV was reduced by partitioning or inactivation at individual steps ranged from 10))-1)) to more than 10))-4)) of in vitro infectious units (IVIU)/ml. The effectiveness of virus removal in the entire process by partitioning and inactivation was calculated to be greater than 1 x 10((15)) IVIU/ml.

Concentrations of infectious HTLV-III/LAV in plasma of infected persons have been estimated to be less than 100 IVIU/ml. Further, FDA scientists have shown that the geometric mean infectivity titer of plasma from 43 HTLV-III/LAV infected persons was 0.02 IVIU/ml (4).

Thus, the margin of safety based on the removal of infectivity by the fractionation process is extremely high. Scientists at CDC and FDA also cultured 38 lots of HBIG, IVIG, and IG, most of which contained HTLV-III/LAV antibody. HTLV-III/LAV was not recovered from any lot tested.

Reported by J Bossell, MD, Cornell University, New York City; Central Laboratories Swiss Red Cross Blood Transfusion Svc, Berne, Switzerland; Immuno A.G., Vienna, Austria; KabiVitrum AB, Stockholm, Sweden; Massachusetts Public Health Biologics Laboratories, Boston, Massachusetts; Miles Laboratories, Inc., Berkeley, Travenol Laboratories, Inc., Glendale, California; Center for Drugs and Biologics, U.S. Food and Drug Administration; Center for Infectious Diseases, CDC.

Editorial Note: The laboratory and epidemiologic studies referred to have shown that concern about HTLV-III/LAV infection associated with the use of immune globulins available in the United States is not warranted. Strategies for using immune globulins recommended by the Immunization Practices Advisory Committee should be followed (5).

Recently, concern has been expressed that patients who received IG prepared from plasma of donors not screened for HTLV-III/LAV antibody may have a passively acquired false-positive reaction for antibody (6). Passively acquired HTLV-III/LAV antibody from HBIG known to contain high levels of antibody has been reported (3). Based on the estimated half-life of globulins in plasma, it can be calculated that passively acquired antibodies might be detected in sera of recipients for as long as 6 months after administration of immune globulins. It is important to recognize this possibility when attempting to determine the significance of HTLV-III/LAV antibody in a person who has recently received immune globulins, especially HBIG.

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APPENDIX X

19 CSR 20-20.020 Reporting Communicable Diseases

PURPOSE: This rule designates the diseases, disabilities and conditions that must be reported to the Department of Health. It also establishes when they must be reported.

(1) Category I diseases must be reported to the Department of Health or to the local health authority within twenty-four (24) hours of suspected diagnosis by telephone, telegraph or other rapid communication, followed by a written report within seven (7) days. Category I diseases are: Animal bites; Botulism; Chlamydia trachomatis infections; Diphtheria; Epidemics -- foodborne, toxic substances and others; Gonorrhea; Measles; Meningitis, Haemophilus influenzae; Meningitis, Meningococcal; Poliomyelitis; Rabies; Rubella; Syphilis and Typhoid Fever.

(2) Category II diseases must be reported to the Department of Health or to the local health authority in writing within seven (7) days of suspected or established diagnosis. Category II diseases are:

Acquired immune deficiency syndrome (AIDS);
Amebiasis;
Anthrax;
Brucellosis;
Campylobacter infections;
Chancroid;
Chickenpox
Cholera;
Encephalitis, infectious;
Encephalitis, viral;
Genital herpes;
Giardiasis;
Granuloma inquinale;
Hepatitis A, B, and non-A, non-B;
Histoplasmosis outbreaks;
Influenza outbreaks;
Kawasaki disease;
Legionellosis;
Leptospirosis;
Lymphogranuloma venereum
Malaria;
Meningitis, aseptic;
Mumps;
Nongonococcal urethritis;
Nosocomial outbreaks;
Pediculosis outbreaks;
Pertussis;
Plague;
Psittacosis;
Reye's syndrome;
Rocky Mountain spotted fever;
Salmonella infections
Scabies outbreaks;
Shigella infections;
Tetanus;
Toxic shock syndrome;
Trichinosis;
Tuberculosis
Tularemia

(3) Diseases and illnesses resulting from exposure to a toxic substance or to a radioactive substance that are indicative of an occupational health, public health or environmental problem must be reported to the Department of Health or the local health authority. If such a disease or illness is verified or suspected and presents an emergency or serious threat to public health or safety, that report shall be made by telephone, telegraph or other rapid communication followed by a written report. Diseases or illnesses resulting from exposure to toxic substances that must be reported include, but are not limited to, the following; occupational lung disease including silicosis, asbestosis and byssinosis; occupationally-related cancers including mesothelioma; and illnesses or diseases related to pesticide poisoning.

(4) The occurrence of epidemics or outbreaks of any illness or disease which may be of public health concern shall be reported to the Department of Health or the local health authority by telephone, telegraph or other rapid communication within twenty-four (24) hours of suspected diagnosis followed by a written report within seven (7) days.

(5) A physician attending any person who is suffering from any disease or condition listed in sections (1) through (4) of this rule or who is suspected of having any of those diseases or conditions, or who is suspected of being a carrier of any of those diseases or conditions shall report to the Department of Health or the local health authority that person's name, address, age, sex, race, name of disease or condition diagnosed or suspected and the date of onset of the illness.

(A) A physician attending any patient, with any disease or condition listed in sections (1) through (4) of this rule, who is in a hospital, clinic or other private or public institution may authorize, in writing, the administrator, superintendent or the person in charge of the hospital, clinic or institution to submit reports of communicable diseases on patients attended by the physician at the hospital, clinic or institution. But under no other circumstances shall the physician be relieved of this reporting responsibility. Each report shall include the name, age, sex, race and the address of the patient, the disease diagnosed or suspected, the date of onset of illness, and whether the patient is hospitalized. If the patient is hospitalized, the name and address of the hospital, date of the report, the name and address of the attending physician, and any appropriate laboratory results must be included in the report.

(B) A physician's report of epidemics as required in section (4) of this rule shall include the diagnosis or principal symptoms, the approximate number of cases, the local health authority jurisdiction within which the cases occurred and the name and address of the reporting physician.

(6) Any person in charge of a public or private school, summer camp or day care center shall report immediately to the local health authority the presence or suspected presence of any diseases listed in sections (1) through (4) of this rule.

(7) All local health authorities shall forward to the Department of Health reports of all diseases listed in sections (1) through (4) of this rule. Any report shall be forwarded within twenty-four (24) hours after it is received, according to procedures established by the Department of Health director. A local health authority shall transcribe from any original report the information necessary to carry out the required duties in 19 CSR 20-20.020(2),(3) and (3)(A).

(8) All individual morbidity reports received by a local health authority or the Department of Health are to be considered confidential records and not public records.

Auth: section 192.020, RSMo(1978). Original rule filed July 15, 1948, effective Sept. 13, 1948.Amended: Filed Sept. 1, 1981, effective Dec. 11, 1981. Rescinded and readopted: Filed Nov. 23, 1982, effective March 11, 1983. Emergency amendment filed June 10, 1983, effective June 20, 1983, expired Sept. 10, 1983. Amended: Filed June 10, 1983, effective Sept. 11, 1983. Amended: Filed Nov.4, 1985. Effective March 24, 1986.

DEPARTMENT OF MENTAL HEALTH REFERRAL CENTERS

APPENDIX XI

St. Joseph State Hospital
St. Joseph, MO 64501
816/232-8431

Western MO MHC
600 E. 22nd St.
Kansas City, MO 64111
816/472-3000

Swope Parkway MHC
4900 Swope Parkway
Kansas City, MO 64130
816/923-5300

Community MHC South
11131 Colorado
Kansas City, MO 64137
816/765-9440

Comp. MH Services, Inc.
10901 Winner Rd.
Independence, MO 64052
816/254-3652

Tri-Co MHC
2900 Hospital Drive
North Kansas City, MO 64116
816/474-5747

West Central MO HC
Burkath Road
Warrensburg, MO 64093
816/747-7127

Nevada State Hospital
Nevada, MO 64772
417/667-7833

Ozark MHC
P. O. Box 2526
Joplin, MO 64803
417/781-2410

Burrell MHC
P. O. Box 2611 SSS
Springfield, MO 65806
417/866-1969

Services 11 Board
Family MHC, 1905 Stadium
Jefferson City, MO 65101
314/634-3000

Mid-Mo MHC
#3 Hospital Drive
Columbia, MO 65201
314/449-2511

Northcentral MO MHC
P. O. Box 30
Trenton, MO 64683
816/359-4487

Mark Twain MHC
P. O. Box 708
Hannibal, MO 63401
314/221-2120

Fulton State Hospital
Fulton, MO 65251
314/642-3311

Four Counties MHC
2747 W. Clay St., Su. A
St. Charles, MO 63301
314/946-4000

Farmington State Hospital
Farmington, MO 63640
314/756-6792

Ozark Area Care & Counseling
402 S. First
Houston, MO 65483
417/967-2438

SE Ozark MHC
209 S. Main
Poplar Bluff, MO 63901
314/686-1123

Bootheel MHC
P. O. Box 1043
Sikeston, MO 63801
314/472-0800

St. Francis MHC
211 St. Francis Dr.
Cape Girardeau, MO 63701
314/334-1100

Community Treatment, Inc.
P. O. Box 505, Main & Mill St.
Fetus, MO 63028
314/937-3300

Gr. Rivers MH Services
601 S. Brentwood Blvd.
Clayton, MO 63105
314/854-6350

Yeatman/Union Sarah MHC
4731 Delmar Blvd.
St. Louis, MO 63108
314/362-8800

Malcolm Bliss MHC
1420 Grattan
St. Louis, MO 63108
314/241-7600

St. Louis State Hospital
5400 Arsenal
St. Louis, MO 63139
314/644-8000